EXHIBIT L

Report of Professor Thomas McGuire

Regarding Public Nuisance

March 25, 2019

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I. Introduction

A. Qualifications

1. My name is Thomas McGuire and I am a Professor of Health Economics in the Department of Health Care Policy at Harvard Medical School, where I teach health economics in Harvard University's Ph.D. Program in Health Policy. In 2008, I received the Everett Mendelsohn Excellence in Mentoring Award from Harvard's Graduate School of Arts and Sciences. I received an A.B. degree from Princeton University in 1971 and a Ph.D. degree in economics from Yale University in 1976.

2. I am a member of the National Academy of Medicine – formally, the Institute of Medicine (IOM) – and a Research Associate at the National Bureau of Economic Research. I served for ten years as an editor of the leading journal in the field of health economics, the *Journal of Health Economics* and co-edited the *Handbook of Health Economics*, Volume II.

3. For more than 40 years I have conducted research on the economics of managed care, health insurance, health care payment systems, drug pricing and procurement, the economics of health care disparities by race and ethnicity, and the economics of behavioral healthcare. I have recently authored a series of published papers on the economics of drug prices, competition between branded and generic drug products, and insurance coverage for drugs.[1] I

[1] T.G. McGuire and S. Bauhoff, "Adoption of a Cost-Saving Innovation: Germany, UK and Simvastatin," in N. Klusen, F. Verheyen, and C. Wagner, eds., *England and Germany in Europe – What Lessons Can We Learn from Each Other?* Baden-Baden, Germany: Nomos, 2011, pp. 11-26; E.R. Berndt, T.G. McGuire, and J.P. Newhouse, "A Primer on the Economics of Prescription Pharmaceutical Pricing in Health Insurance Markets," *Forum for Health Economics & Policy*, 14(2), 2011, Article 10; J. Glazer and T.G. McGuire, "A Welfare Measure of 'Offset Effects' in Health Insurance," *Journal of Public Economics,* 96, 2012, pp. 520-523; J. Glazer, H. Huskamp, and T.G. McGuire, "A Prescription for Drug Formulary Evaluation: An Application of Price Indexes," *Forum for Health Economics and Policy*, 15(2), 2012, Article 3; K. Drake, M. Starr, and T. McGuire, "Do 'Reverse Payment' Settlements Constitute an

co-chaired three conferences on the Industrial Organization of Health Care and edited special sections of economic journals in which the conference papers were published.[2] My research has been recognized by a number of awards, including the Victor Fuchs Lifetime Achievement Award for 2018, awarded by the American Society of Health Economics.[3] In 2015, a jointly authored paper on reverse payment settlements in the drug industry received the Article of the Year Award from the *International Journal of the Economics of Business*.[4]

4. I have conducted research and contributed to public policy regarding behavioral health (mental and addictive illnesses) for 40 years. I was the co-chair of four conferences on economics and mental health sponsored by the National Institute of Mental Health (NIMH). I have been the recipient of investigator-initiated research projects (R01's) from the NIMH and the National Institute on Drug Abuse (NIDA). My research in behavioral health has earned a number of awards, including the Elizur Wright Award from the American Association of Risk and

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Anticompetitive Pay-for-Delay?" *International Journal of the Economics of Business,* 22(2), 2015, pp. 173-200; T. McGuire, K. Drake, E. Elhauge, R. Hartman, and M. Starr, "Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements," *Iowa Law Review*, 101(4), 2016, pp. 1581-1599; and K. Drake and T. McGuire, "Stock-Price Evidence for Anticompetitive Effects in the Nexium 'Reverse-Payment' Settlement," *Journal of Competition Law & Economics*, 12(4), 2016, pp. 735-747.

[2] T.G. McGuire and M.H. Riordan (guest editors), "The Industrial Organization of Health Care," *Journal of Economics & Management Strategy*, 3(1), March 1994; A. Ma, T.G. McGuire, and M.H. Riordan (guest editors), "The Industrial Organization of Health Care, II," *Journal of Economics & Management Strategy*, 6(1), Spring 1997; and A. Ma and T.G. McGuire (guest editors), "The Industrial Organization of Health Care, III," *Journal of Economics & Management Strategy*, 8(3), Fall 1999.

[3] Two of my jointly authored papers received "Best Paper of the Year" awards in 2008, one from Academy Health for research on physician-patient interaction and one from the National Institute for Health Care Management for work on incentives in managed care plans. My paper on designing payment systems for private health insurance markets received the best paper of the year award in 2014 from the National Institute for Health Care Management.

[4] K. Drake, M. Starr, and T. McGuire, "Do 'Reverse Payment' Settlements Constitute an Anticompetitive Pay-for-Delay?" *International Journal of the Economics of Business,* 22(2), 2015, pp. 173-200.

Insurance recognizing "an outstanding contribution to the literature on risk and insurance" for my *Financing Psychotherapy* (1981), and the Carl Taube Award from the American Public Health Association for "outstanding contributions to public health" (1991). I have supervised numerous Ph.D. dissertations on the economics of behavioral health at Boston University, Brandeis University and Harvard University. I was the director of two NIMH-funded pre- and post-doctoral training programs in the economics of mental health and the economics of mental health policy. My research has directly contributed to the design of health insurance and provider payment in behavioral health care.

5. My litigation experience includes recent testimony at two drug industry antitrust trials.[5] Appendix A contains my CV and a list of my recent testimony. My rate of compensation in this matter is $900 per hour. My compensation does not depend upon the outcome of this litigation.

B. Assignment

6. In connection with the public nuisance claims raised by Cuyahoga County and Summit County (Bellwether Plaintiffs), I have been asked the following three questions:[6]

[5] *In re: Nexium (esomeprazole) Antitrust Litigation*, United States District Court for the District of Massachusetts, MDL No. 2409, Civil Action No. 112-cv-11711, November 7 and 20, 2014, and *In re: Solodyn (Minocycline Hydrocholoride) Antitrust Litigation*, United States District Court, District of Massachusetts, MDL No. 14-md-2503-DJC, March 26-27, 2018.

[6] I have not been asked to offer an opinion on the scope or cost of programs needed to abate this nuisance, but such a report could be submitted at such time as the Court deems appropriate.

- First, is there a framework within the area of applied microeconomics by which economists determine the existence of, and measure the extent of, what is known under the law as a "public nuisance?"
- Second (and if the answer above is "yes"), do you have an opinion to a reasonable degree of certainty in the area of applied microeconomics as to whether there is a public nuisance that resulted from the shipment of prescription opioid products into the Bellwether communities over the period 2006 to the present that has impacted those communities?
- Third (and if the answer above is "yes"), do you have an opinion of the magnitude of the economic costs imposed on the Bellwether communities over the period 2006 to 2016, the most recent period for which data are fully available, taking into account any potential economic benefits with respect to the shipments?

7. Because these questions are framed in the context of the legal term "public nuisance," I have been instructed by counsel to be guided by the following general definition of a public nuisance:

> "The definition of 'public nuisance' . . . is couched in broad language. According to the Restatement [(Second) of Torts], a 'public nuisance' is 'an unreasonable interference with a right common to the general public.' . . . 'Unreasonable interference' includes those acts that significantly interfere with public health, safety, peace, comfort, or convenience, conduct that is contrary to a statute, ordinance, or regulation, or conduct that is of a continuing nature or one which has produced a permanent or long-lasting effect upon the public right, an effect of which the actor is aware or should be aware."[7]

[7] *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002). In that case, involving a public nuisance claim against the gun industry, the Court held that "the city should be permitted to bring suit against the manufacturer of a product under a public nuisance theory, when, as here, the product has allegedly resulted in widespread harm and widespread costs to the city as a whole and to its citizens individually (at 1142)."(internal

8. Coupled with this general definition of public nuisance, I have further been instructed by counsel to be guided by the Bellwether Plaintiffs' allegations regarding their public nuisance claims. I understand that this Court has already recognized that the Bellwether Plaintiffs' public nuisance claims "allege that Defendants created and maintained a public nuisance in the marketing and distribution of prescription opioids."[8] Furthermore, I understand the Bellwether Plaintiffs have specifically alleged that the "Defendants have created and maintained a public nuisance by marketing, distributing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's Community, and Plaintiff and the residents of Plaintiff's Community have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property."[9]

9. I further understand that the Bellwether Plaintiffs allege that "Defendants have created and maintained an absolute public nuisance through their ongoing conduct of marketing, distributing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiffs' communities, flooded Plaintiffs' communities with opioids, and facilitated and encouraged the flow and diversion of

quotations omitted). Also see *City of Cincinnati v. Deutsche Bank Nat'l Trust Co.*, 863 F.3d 474, 477 (6th Circuit 2017) ("Under Ohio law, a common law public nuisance is an unreasonable interference with a right common to the general public.") (internal quotations omitted).

[8] *See* Magistrate Judge David Ruiz's Report and Recommendation, October 5, 2018 at p. 60.

[9] Cuyahoga County, Second Amended Complaint, ¶ 1024. Similarly, see Second Amended Complaint (Summit County), ¶ 1000.

opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs and the residents of Plaintiffs' communities."[10]

10. I will use the term "Defendants' shipments of prescription opioids," or sometimes just "shipments," as a shorthand for the activity the Bellwether Plaintiffs claim constitutes a public nuisance regarding both the marketing and distribution of prescription opioids by Defendants.

C. Overview of Structure and Organization of the Report

11. In Section II, I discuss the economic analysis of a public nuisance and its relationship to an analysis of externalities. Included in this section is a discussion of the nature of negative externalities associated with shipments of prescription opioids, the role of the presence of positive effects of opioid use, and examples of public response to negative externalities. In Section III, I identify a series of harms caused by opioid shipments and quantify them for the Bellwether communities. Note that these harms are due directly to the use of prescription opioids and, indirectly, by use of non-prescription opioids (*e.g.*, heroin, fentanyl) caused by the shipments. I limit my discussion to five groups of harms: mortality, morbidity, neonatal abstinence syndrome, crime, and child maltreatment. In Section IV of this Report, I monetize these harms to the Bellwether communities. In this monetization, I also include damages incurred by the Cuyahoga and Summit County governments as calculated in my Report on damages.

[10] Corrected Second Amended Complaint (Summit County), ECF No. 514, ¶ 1002. Similarly, see Cuyahoga County, Second Amended Complaint, ¶1026.

12. Attached to this Report are a series of appendices which detail my analysis and are identified throughout this Report. In addition, throughout the Report, I reference and rely upon the work of other experts who are submitting testimony contemporaneously with this Report.[11]

D. Summary of Opinions

13. First, I am of the opinion that there is a framework within the area of applied microeconomics by which economists can determine the existence of, and measure the extent of, what is known under the law as a "public nuisance." Within economics there is a long tradition of analyzing the social consequences of private behaviors imposing harms on others. This economic framework provides a natural parallel with the legal notion of public nuisance. And such economic analyses are commonly used by decision makers to design policies to contend with private behavior imposing harms.

14. Second, I am of the opinion to a reasonable degree of certainty in the area of applied microeconomics that a public nuisance has resulted from the shipment of prescription opioid products into the Bellwether communities, and that this public nuisance has had a widespread, devastating, and long-lasting impact on both the individual residents of the Bellwether communities and on the Bellwether Plaintiffs themselves. This opinion is entirely consistent

[11] Expert Report of Professor David Cutler (hereafter Cutler Report); Expert Report of Dr. David Egilman; Expert Report of Professor Jonathan Gruber (hereafter Gruber Report); Expert Report of Dr. David Kessler (hereafter Kessler Report); Expert Report of Thomas McGuire regarding Damages (hereafter McGuire Damages Report); Expert Report of Dr. Matthew Perri (hereafter Perri Report); Expert Report of Professor Meredith Rosenthal (hereafter Rosenthal Report); Expert Report of Dr. Schumacher; and Expert Report of Dr. Nancy Young (hereafter Young Report).

with similar analyses sponsored by numerous public and private agencies throughout the United States (albeit typically applicable to broader geographic communities).

15. Third, I am of the opinion, again to a reasonable degree of certainty in the area of applied microeconomics, that the estimated magnitude of the net economic burden imposed on the Bellwether communities over the period 2006-2016 is approximately $20 billion. The major components of this harm, as measured in economic terms, are shown in Table 1. These dollar values of harms are net of any benefits provided by prescription opioid shipments.

Table 1
Summary of Monetary Value of Harms Due to Prescription Opioid Shipments
2006-2016
($millions)

Harms Due to Defendants' Shipments	Cuyahoga	Summit	Total
Excess deaths	$11,279	$5,377	$16,656
Excess morbidity	$1,376	$587	$1,963
Excess neonatal abstinence syndrome	$9	$7	$16
Excess crimes	$327	$126	$453
Excess child maltreatment	$401	$297	$698
Excess costs to Bellwether governments	$172	$99	$271
Totals	***$13,564***	***$6,492***	***$20,056***

Sources: Tables 5a, 5b, 7a, 7b, 8a, 8b, 9a, 9b, 10a, 10b and 11 of this Report.

II. The Economic Analysis of Public Nuisances

A. Public Nuisance and Negative Externalities

16. I rely on the long tradition within economics of analyzing the social consequences of private behaviors imposing costs on others. A public nuisance, in economic terms, is generally observed when an action (or set of actions) undertaken by a party (or group of parties) gives rise to overwhelming "negative externalities." An externality "occurs whenever the actions of one party make another party worse or better off, yet the first party neither bears the costs nor receives the benefits of doing so."[12]

17. A negative externality imposes costs on others. An example of a negative externality is pollution of a river.[13] If a household or firm deposits waste in the river, other members of the community are harmed (*e.g.*, bear health risks, enjoy less recreational use of the river) but they are not compensated for the costs imposed on them. In economics, harms, such as health risks or loss of recreational opportunities, are regarded as a "cost" imposed on others and can sometimes be valued in dollar terms.

18. The legal concept of a public nuisance parallels the concept of a negative externality in economics. An externality is created when a private actor harms others and does not compensate others for those effects. If the negative externality satisfies the other components of the definition mentioned earlier, it qualifies as a public nuisance. "Nuisance may also be

[12] J. Gruber, *Public Finance and Public Policy*, 5th edition, 2016. p. 124.

[13] An externality can be positive as well, that is, confer benefits on others. A neighborhood association might maintain a local park that is open to the public, benefiting those outside the immediate neighborhood as well as residents of the neighborhood.

viewed as a form of externality that interferes with the enjoyment or use of another's property."[14] The economic framework of an externality provides a natural parallel with the legal notion of a public nuisance.[15]

19. In a related approach, scholarship in law and economics has sometimes referred to a public nuisance as a "public bad": "The common law of public nuisance has evolved for dealing with public bads. When an agent imposes a cost, similar in amount and kind, on a group of individuals, then the harmed group can call upon a public defender to bring a public nuisance action against the agent."[16] "Public bads are . . . said to emerge when a large number of parties are affected negatively and simultaneously, at the margin, by an action undertaken by an individual or group. The nature of the phenomenon is such that there is no low-cost way to insulate and partition the affected individuals in the group from the negative effect. What one group member receives, all receive."[17] Public bads are a form of negative externality, and I will

[14] T. Swanson and A. Kontoleon, "Nuisance (Section 2100)," in B. Bouckaert and G. de Geest (eds.), *Encyclopedia of Law and Economics*, 2000, pp. 380-402. See also, R. Cooter and T.S. Ulen (2016), *Law and Economics*, *6*th *Edition*, Berkeley Law Books, 2, p. 183.

[15] I have been instructed by counsel that unlike a private nuisance, a public nuisance does not necessarily involve interference with the use and enjoyment of land because a common law nuisance is the doing of or the failure to do something that injuriously affects the safety, health or morals of the public, or works some substantial annoyance, inconvenience or injury to the public. See Restatement (Second) of Torts (1977) § 821B (at common law, a public nuisance is defined as an unreasonable interference with rights held by the public in general, not merely with the rights or interests of a few individuals). I also understand that a public nuisance suit may be brought either by the state through its attorney general or through another public official or public agency representing the state or one of its political subdivisions through a statutory public nuisance claim, and that Cuyahoga and Summit counties both have such claims against Defendants here.

[16] K. Boudreaux and B. Yandle, "Public Bads and Public Nuisance-Common Law Remedies for Environmental Decline," *Fordham Environmental Law Review*, 14(1) Article 2, 2002, pp. 55-88.

[17] *Ibid.*, p. 59-60.

use the more general term "negative externality" to characterize a public nuisance in economic terms.[18]

B. Prescription Opioids are Not a Typical Consumer Good

20. Patients do not choose prescription drugs for themselves. Generally, physicians decide the drug, dosage, and duration to prescribe to patients. Since the dawn of modern health economics associated with the classic article from Nobel Prize-winner Kenneth Arrow, economic analysis has recognized the special role of the physician in formulating patient demand for health care.[19] The role of the physician remains a central and widely studied issue in health economics.[20] While generally regarded as making medical decisions on the basis of patient health outcomes, physicians are recognized, however, to be "imperfect agents" for

[18] The relationship between public bad and negative externality is the same as between public good and positive externality. A public good involves positive externalities, but all externalities are not public goods. Pure public goods must be consumed in equal quantity by all and are completely non-rivalrous, *i.e.*, the consumption by one person does not affect the consumption by others. The classic papers are: P.A. Samuelson, "The Pure Theory of Public Expenditure," *Review of Economics and Statistics,* 36, 1954, pp. 386-389, and P.A. Samuelson, "Diagrammatic Exposition of a Theory of Public Expenditure," *Review of Economics and Statistics,* 37,1955, pp. 350-356. Not all externalities possess these two characteristics in pure form so I use the more general term, "externality."

[19] K. Arrow, "Uncertainty and the Welfare Economics of Medical Care," *American Economic Review*, 53(5), December 1963, pp. 941-73.

[20] For example, see T.G. McGuire, "Physician Agency," *in* A.J.Culyer and J.P. Newhouse (eds), *Handbook of Health Economics*, 2000, chapter 9; G. Mooney and M. Ryan, "Agency in Health Care: Getting Beyond First Principles," *Journal of Health Economics*, 12(2), July 1993, pp. 125-135; S. Vick and A. Scott, "Agency in Health Care: Examining Patients' Preferences for Attributes of the Doctor-Patient Relationship," *Journal of Health Economics*, 17(5), October 1998, pp. 587-605; and K.R. Brekke, R. Nuscheler, and O.R. Straume, "Gatekeeping in Health Care," *Journal of Health Economics*, 26(1), 2007, pp. 149-170.

patients, partly for reasons related to information[21] and partly for reasons related to incentives.[22]

21. In practice, to decide about prescription drugs, physicians are influenced by "detailing" visits by representatives of brand drug companies and other promotional activities by drug companies.[23] Brand-name drug companies spend mightily on these visits,[24] and undertake

[21] To take just one aspect of this, physicians must make decisions about drug treatment based on symptom reports and clinical tests, both of which can be unreliable. Physicians make decisions based on population-wide prevalence of disorders, decisions that may not be best for the particular patient. See A. Balsa, T. McGuire and L. Meredith, "Testing for Statistical Discrimination in Health Care," *Health Services Research*, 40(1), 2005, pp. 227-252.

[22] For a general discussion, see J. Newhouse, *Pricing the Priceless: A Health Care Conundrum*, Cambridge, MA: MIT Press, 2002. One special form "incentives" in the pharmaceutical area are financial rewards manufacturers confer on physicians who liberally prescribe their product. For example, Hadland *et al.* find that there was greater opioid prescribing under Medicare Part D by physicians who received non-research-based payments related to opioid products (S.E. Hadland, *et al.*, "Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians with Subsequent Opioid Prescribing," published online at jamainternmed.2018.1999, May 14, 2018). For another example, the New York State Health Foundation found that "Physicians who received payments from opioid manufacturers prescribed more opioids to Medicare patients than physicians who did not receive any opioid-related payments." They also found that "a higher number of opioid prescriptions was associated with more opioid-related payments to physicians" (New York State Health Foundation, "Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State," June 2018).

[23] For example, see P. Manchanda and P. Chintagunta, "Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis," *Marketing Letters*, 15(2-3), 2004, pp. 129-145; F. Gönül, *et al.*, "Promotion of Prescription Drugs and Its Impact on Physicians' Choice Behavior," *Journal of Marketing*, 65(3), July 2001, pp. 79-90; A. Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *Journal of the American Medical Association*, 283(3), January 19, 2000, pp. 373-80; A. Fugh-Berman, "The Corporate Coauthor," *Journal of General Internal Medicine*, 20(6), June 2005, pp. 546-48; Editorial Staff, "Pharmaceutical Marketing to Physicians: Free Gifts Carry a High Price," *American Medical News*, June 10, 2002; P. Azoulay, "Do Pharmaceutical Sales Respond to Scientific Evidence?" *Journal of Economic & Management Strategy*, 11(4), Winter 2002, pp. 551-594; J. Avorn, M. Chen, and R. Hartley, "Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *American Journal of Medicine*, 73(1), July 1982, pp. 4-8; C. DeJong, *et al.*, "Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries," *JAMA Internal Medicine,* 2016, 176(8), pp. 1114-22; I. Larkin, *et al.*, "Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing," *JAMA*, 2017, 317(17), pp. 1785-95; A. Datta and D. Dave, "Effects of Physician-Directed Pharmaceutical Promotion on Prescription Behaviors: Longitudinal Evidence," *Health Economics*, 26, 2017, pp. 450-68; and G. Spurling, *et al.*, "Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review," *PLOS Medicine*, 7(10), October 2010.

[24] For example, see Congressional Budget Office (CBO), "Promotional Spending for Prescription Drugs," December 2, 2009; Families USA, "Off the Charts: Pay, Profits and Spending by Drug Companies," Families USA Publication No. 01-104, July 2001, pp. 1-31 at 1; and M. Hurwitz and R. Caves, "Persuasion or Information? Promotion and the

huge numbers of detailing visits.[25] Drug company promotional efforts can go too far, and have been put in check by national reporting requirements and ethical guidelines imposed by private organizations that limit payments and even contacts with pharmaceutical representatives.[26] In the context of prescription opioids, manufacturers were purveying biased information. As explained in the expert report of Dr. Matthew Perri, the information doctors were being given about the dangers of prescription opioids was in most cases false, and systematically and intentionally misleading.[27] Dr. Perri's report establishes, among other things, that (i) manufacturers of prescription opioids are sophisticated marketers who are skilled in applying marketing strategies and tactics to successfully target and reach their desired customers, (ii) these Defendants target multiple audiences, including patients, prescribers, insurers, formulary decision makers, wholesalers, and pharmacies, (iii) this marketing of prescription opioids expanded demand for these drugs, with increases in the volume of doses sold and the numbers of patients treated with opioids, (iv) the addictive properties of opioids make marketing of such products especially problematic because of the likelihood that market demand may be driven by tolerance, dependence, abuse or addiction, and (v) in the context of addictive substances,

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Shares of Brand Name and Generic Pharmaceuticals," *Journal of Law and Economics*, 31(2), October 1988, pp. 299-320 at 302.

[25] From 1993 to May 2018, opioid drug manufacturers made over 10 million detailing visits (see Rosenthal Report, Attachment C).

[26] See National Conference of State Legislatures, "Marketing and Advertising of Pharmaceuticals," November 5, 2018, available at http://www.ncsl.org/research/health/marketing-and-advertising-of-pharmaceuticals.aspx. Also see Centers for Medicare & Medicaid Services (CMS), Open Payments page, available at https://www.cms.gov/openpayments/ ("Open Payments is a national disclosure program … making the financial relationships between applicable manufacturers and group purchasing organizations (GPOs) and health care providers (physicians and teaching hospitals) available to the public.").

[27] Perri Report, Section III.C.

as these prescriptions of opioids are, expansion of demand is not an appropriate use of marketing.[28]

22. As a result, the ultimate "consumers" of prescription opioids (patients) were not properly informed about the risk of harms associated with prescription opioids because their doctors were systematically misled by manufacturers. Without full knowledge of harms, a consumer cannot take them into account, nor can the consumer weigh the harms and costs relative to any purported benefits. Consumers could not accurately anticipate prescription opioids' addictive properties because their agents, *i.e.*, physicians, were misled by Defendants.

C. Benefits from Shipments and Positive Externalities

23. A product (like prescription opioids) even while harming users through inappropriate use and harming others by imposing negative externalities, might at the same time confer positive benefits on particular individuals when used in accordance with scientifically acceptable clinical criteria, and furthermore might, in those circumstances, generate positive externalities to others.

24. A comprehensive evaluation of a public nuisance from an economic perspective considers both the positive and negative effects of the potential public nuisance. The empirical framework I apply in this Report recognizes and quantifies not only costs in economic terms, but also the ostensible benefits to both to the user, and to the wider economy, from the use of prescription opioids based on scientifically acceptable clinical criteria. Consideration of both benefits and costs allows for a net accounting in which benefits can be weighed against costs.

[28] Perri Report, Section III.

D. Widespread Negative Externalities to Public Health are Often Addressed by Public Policy

25. The economic characteristics of widespread negative externalities (or public bads) generally mean that to contend with the negative externality, public action is needed. No single individual has the incentives or is in a position to respond forcefully and efficiently to a problem affecting large shares of the population. Collective action, led by government, is needed to effectively address the crisis. In economic terms, collective action is generally necessary when the social harm takes the form of a large-scale negative externality.[29]

26. There are many examples, within public health, of collective action, led by government, to contend with widespread negative externalities. Outside of the context of the opioid crisis, this includes taxation of goods such as cigarettes and alcohol, bans on use of alcohol and other goods by vulnerable age groups, and bans on consumption in certain locations (*e.g.*, smoking in restaurants or consumption of alcohol in public).

27. I note that not all activities that might lead to a significant imbalance, in economic terms, between overwhelming costs versus benefits are treated under the law as a public nuisance requiring sweeping government intervention to abate its existence. For example, while I have not conducted the analysis, one might surmise that an economic weighing of the benefits versus costs of the prevalence of alcohol use yields an overwhelming net cost to society; yet for myriad reasons, society condones the prevalence of alcohol and, subject to its regulation and appropriate use, selling, buying and consuming alcohol are legal activities.

[29] M. Olson, The Logic of Collective Action: Public Goods and the Theory of Groups, Harvard University Press, 1965.

28. For this Report, I have been advised by counsel that the Bellwether Plaintiffs intend to prove that the public nuisance regarding the shipment of prescription opioids arose in substantial part from *the unlawful conduct* by the Defendants. As a result, I understand from counsel that the public nuisance described here does not fall within some area of condoned societal harm. Indeed, even in areas where society tolerates some significant harm from an activity, if the prevalence of that activity is expanded through illegal means, it might give rise to a public nuisance.

29. The opioid crisis itself yields numerous examples of governmental actions required by its existence. I review a few of these examples here from federal activity, but also note that collective action has been led by government at the state and local level as well.[30] My examples do not constitute a comprehensive list of government policy responses.

30. The executive branch of the federal government has taken action, under both the current and the previous administration, to address the opioid crisis. In March 2015, the now former Secretary of HHS (U.S. Department of Health and Human Services), Sylvia Burwell,

[30] According to the National Center for State Courts (NCSC), "State legislatures have been active in developing and enacting a broad range of statutory responses to the opioid crisis," (https://www.ncsc.org/Topics/Court-Management/Leadership-and-Change-Management/Opioids-and-the-Courts.aspx). For example, according to the Centers for Disease Control and Prevention (CDC), "In 2011 and 2012 respectively, Ohio and Kentucky mandated clinicians to review prescription drug monitoring program (PDMP) data and implemented pain clinic regulation. In these states, MME [morphine milligram equivalent] per capita decreased in 85% and 62% of counties, respectively, from 2010 to 2015," available at CDC, Opioid Overdose (available at https://www.cdc.gov/drugoverdose/policy/successes.html). For another example, in Ohio, Summit County and the City of Akron have implemented community outreach programs directed as suspected opioid addicts (see G. Mace, "Cuyahoga Falls police, fire join with drug counselors to visit homes of addicts to offer help," *Akron Beacon Journal*, January 14, 2017; P. Schleis, "Stow is the Latest Community to Form Quick Response Team to Get Help to Opiate Addicts," *Akron Beacon Journal*, February 15, 2017 and D. Livingston, "Akron adopts quick response team to curb future drug overdoses," *Akron Beacon Journal*, February 28, 2017). In Cuyahoga County the Drug Court Program was started in 2009 to divert convicted drug addicts from jail to treatment (see Cuyahoga County Opiate Task Force Report, 2014, available at http://opiatecollaborative.cuyahogacounty.us/pdf_OpiateCollaborative/en-US/CC_OpiateTaskForceReport.pdf).

launched the HHS Opioid Initiative.[31] The initiative focused on "three priority areas:" improving opioid prescribing practices, expanding the use of naloxone to prevent opioid overdoses, and expanding access to medication-assisted treatment (MAT) to treat opioid use disorders.[32] As part of the Opioid Initiative, the Centers for Disease Control and Prevention (CDC) expanded its new Prescription Drug Overdose Prevention for States program. This program's primary goal was to provide funding to states to enhance their Prescription Drug Monitoring Programs (PDMPs), statewide electronic databases for tracking prescriptions of opioids and other controlled substances.[33]

31. In support of improving prescription practices, the CDC published new opioid prescribing guidelines for primary care clinicians in 2016.[34] In support of expanding the use of naloxone, the initiative promoted states' use of block grants from the Substance Abuse and Mental Health Services Administration (SAMHSA) for purchasing naloxone.[35] In support of expanding access to MAT, the Health Resources and Services Administration granted nearly $100 million to Community Health Centers to expand substance use disorder treatment

[31] U.S. Department of Health and Human Services (HHS), "HHS takes strong steps to address opioid-drug related overdose, death and dependence, March 26, 2015," available at http://wayback.archive-it.org/3926/20170128023910/https://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html.

[32] HHS; Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths," March 26, 2015, available at https://aspe.hhs.gov/system/files/pdf/107956/ib_OpioidInitiative.pdf.

[33] CDC, Prescription Drug Overdose: Prevention for States, CDC-RFA-CE15-1501, May 27, 2015, available at https://www.grants.gov/view-opportunity.html?oppId=274995 and CDC, Prevention for States, October 23, 2017, available at https://www.cdc.gov/drugoverdose/states/state_prevention.html. See also HHS, March 26, 2015, *op. cit.*

[34] D. Dowell, T.M. Haegerich and R. Chou, "CDC Guideline for Prescribing Opioids for Chronic Pain – United States," *JAMA,* 2016, 315(15), pp.1624-1645.

[35] HHS, March 26, 2015, *op. cit.*

services, including MAT, and SAMHSA awarded grant funding to states to expand MAT services.[36]

32. HHS also took action under the Trump administration to combat the opioid epidemic, introducing its Five-Point Opioid Strategy in April 2017.[37] The primary goals of this strategy included: 1) improving access to prevention, treatment, and recovery services; 2) improving public health data reporting; 3) improving treatment practices for pain management; 4) better targeting naloxone and other overdose reversing drugs availability; and 5) new research on pain and addiction. As part of this strategy, the National Institutes of Health (NIH) launched the Helping to End Addiction Long-Term (HEAL) Initiative in 2018 to speed development of non-addictive pain treatments and improve prevention and treatment for opioid addiction.[38]

33. In October 2017, Eric Hargan, the Acting Secretary of HHS, declared a public health emergency in response to the opioid crisis.[39] The public health emergency, more limited than a national state of emergency, grants the federal government some additional flexibility in

[36] Office of the Press Secretary, The White House, "Fact Sheet: Obama Administration Announces Additional Actions to Address the Prescription Opioid Abuse and Heroin Epidemic," March 29, 2016, available at https://obamawhitehouse.archives.gov/the-press-office/2016/03/29/fact-sheet-obama-administration-announces-additional-actions-address. Also see HHS, 2015, *op. cit.*

[37] HHS, "Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis," October 26, 2017, available at https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html and HHS, "5-Point Strategy to Combat the Opioid Crisis," August 7, 2018, available at https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.

[38] National Institutes of Health (NIH), "NIH HEAL Initiative: Enhance Pain Management," December 28,2018, available at https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative/enhance-pain-management.

[39] HHS, October 26, 2017, *op. cit.* Also see J. Johnson and J. Wagner, "Trump declares the opioid crisis a public health emergency," *The Washington Post*, October 26, 2017, available at https://www.washingtonpost.com/news/post-politics/wp/2017/10/26/trump-plans-to-declare-the-opioid-crisis-a-public-health-emergency/?utm_term=.9097d816a96b.

responding to the crisis, including waiving some regulations and allowing states to use federal grant funds to combat opioid abuse.

34. The legislative branch of the federal government has also initiated action in response to the opioid crisis. In addition to including $1 billion in funding to combat the opioid epidemic as part of the 21st Century Cures Act in 2016,[40] Congress has passed two pieces of legislation: the Comprehensive Addiction and Recovery Act of 2016 and the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018.[41]

35. The Comprehensive Addiction and Recovery Act, signed into law by President Obama in 2016, addressed the opioid epidemic in several ways. Among a host of other measures, it created grant programs to improve naloxone availability; expanded access to evidence-based treatment, including MAT; and reauthorized grant programs for states to implement and expand prescription drug monitoring.[42]

36. The SUPPORT for Patients and Communities Act passed in 2018 with broad bipartisan support. Some key provisions of the legislation included promoting more rapid development of

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[40] See SAMHSA, "HHS, SAMHSA to maintain funding formula for $1B opioid grant program," October 30, 2017, available at https://www.samhsa.gov/newsroom/press-announcements/201710300530.

[41] C. Reilly, "President Obama Signs Bipartisan Bill to Combat Opioid Epidemic," *Pew Charitable Trusts,* July 22, 2016, available at https://www.pewtrusts.org/en/research-and-analysis/articles/2016/07/22/president-obama-signs-bipartisan-bill-to-combat-opioid-epidemic. Also see M. Vazquez, "Trump signs opioids law at White House event," *CNN*, October 24, 2018, available at https://www.cnn.com/2018/10/24/politics/donald-trump-opioid-crisis-one-year-later-event/index.html; C.Thompson, "Trump Signs Legislation to Combat Opioid Crisis", *ASHP*, October 25, 2018, available at https://www.ashp.org/news/2018/10/24/trump-signs-legislation-to-combat-opioid-crisis.

[42] C. Reilly, *op. cit.* Also see G. Lopez, "Congress just passed a big bill to fight the opioid epidemic. But there's a catch," *Vox*, July 14, 2016, available at https://www.vox.com/2016/7/6/12101476/obama-congress-opioids-heroin.

non-addictive drugs for pain management, improving PDMPs, and improving coordination across federal agencies to prevent illicit substances like fentanyl from entering the United States.[43] The legislation also had broad implications for Medicaid; in particular, it amended the "long-standing prohibition against the use of federal Medicaid funds for services in Institutions for Mental Diseases (IMDs) for nonelderly adults," allowing Medicaid programs to cover these services for up to 30 days per year for individuals with substance use disorder until September 2023.[44]

37. In addition, as referenced in the expert report of Professor Jonathan Gruber, as early as 2007, law enforcement officials brought actions claiming that manufacturers misrepresented the addictive properties of opioids and that distributors failed to meet their obligations to monitor and report suspicious patterns of shipments.[45] These actions led to substantial settlements, including payments made by (i) Purdue related to criminal and civil charges for misbranding OxyContin with the intent to defraud and mislead the public about its addictive qualities[46] (which also led to three executives at Purdue pleading guilty to misbranding[47]); (ii)

[43] M. Vazquez, *op. cit.* Also see, U.S. Senate Committee on Health, Education, Labor and Pensions, "Chairman Alexander: This Congress, HELP Committee Produced 18 Laws Including 'Landmark' Opioid Legislation to Combat Nation's Most Pressing Public Health Crisis." December 20, 2018, available at https://www.help.senate.gov/chair/newsroom/press/chairman-alexander-this-congress-help-committee-produced-18-laws-including-landmark-opioid-legislation-to-combat-nations-most-pressing-public-health-crisis-.

[44] M. Musumeci and J. Tolbert, "Federal Legislation to Address the Opioid Crisis: Medicaid Provisions in the SUPPORT Act," Kaiser Family Foundation; October 5, 2018, available at https://www.kff.org/medicaid/issue-brief/federal-legislation-to-address-the-opioid-crisis-medicaid-provisions-in-the-support-act/.

[45] Gruber Report, ¶ 44.

[46] B. Meier, "In Guilty Plea, OxyContin Maker to Pay $600 Million," *The New York Times*, May 10, 2007.

[47] H. Won Tesoriero, "OxyContin Maker Pleads Guilty – Purdue Frederick to Pay $634.5 Million Settlement for Hiding Addiction Risk," *The Wall Street Journal*, May 11, 2007.

McKesson related to allegations that it violated federal reporting provisions for its handling of certain prescription medications regulated by the Drug Enforcement Administration (DEA), and for failing to report excessive sales of their products to pharmacies filling illegal online prescriptions[48]; and (iii) Cardinal Health related to its failures to report suspicious sales and orders of controlled substances to the DEA.[49] More recently, Mallinckrodt also paid a substantial settlement to the Department of Justice for, among other things, its failure to report suspicious sales and orders of controlled substances to the DEA.[50]

III. Shipments of Prescriptions Constituted a Public Nuisance to the Bellwether Communities

A. Introduction

38. To address this portion of my assignment, I consider elements of the definition of a public nuisance contained above (¶¶ 7-8), and establish three conclusions:

1. Shipments significantly interfered with public health, safety, peace and comfort of members of the Bellwether communities with continuing and long-lasting effects;
2. The interference from shipments was unreasonable; and
3. Defendants were or should have been aware of the interference.

[48] Department of Justice (DOJ), Press Release, "McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications," May 2, 2008, available at https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html.

[49] The United States Attorney's Office, Colorado, "Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances," October 2, 2008, available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

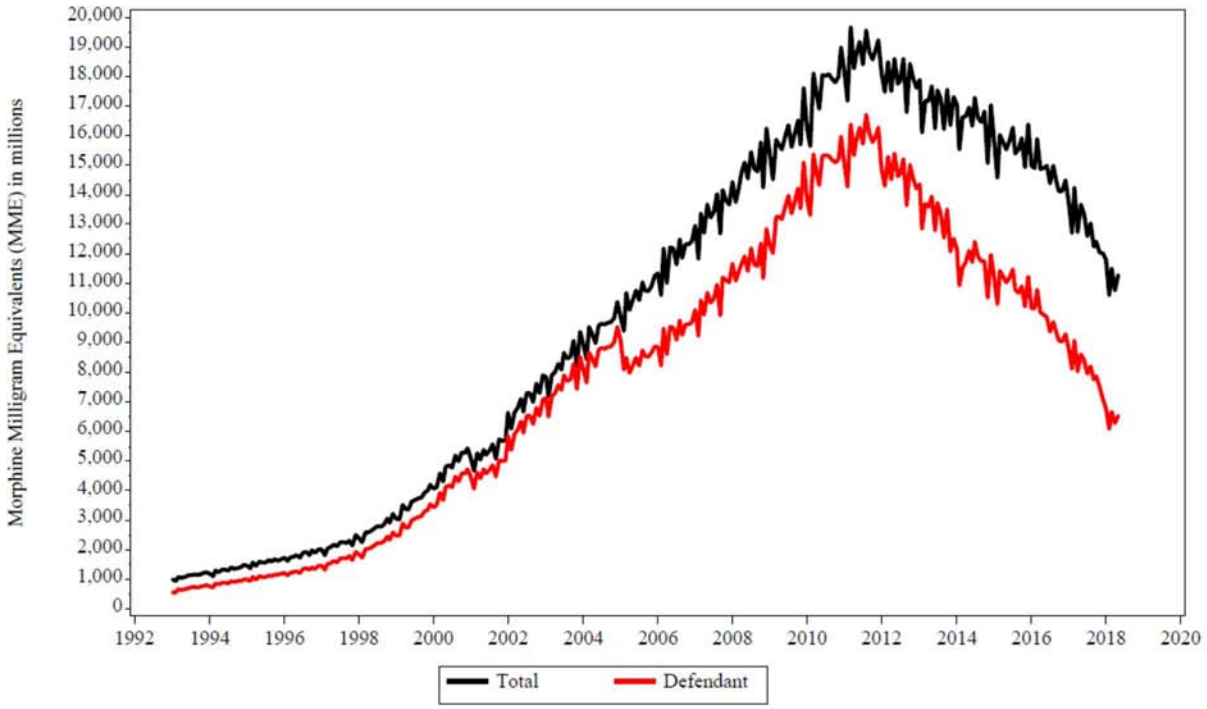
[50] DOJ, Press Release, "Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations,: July 11, 2017, available at https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

39. Before proceeding, it will be useful to briefly identify the Defendants' drugs at issue in this matter. The drugs in the case are Schedule 2 opioids, excluding injectables and all buprenorphine drugs except Butrans, [51] manufactured and distributed by the Defendants. The Defendants account for the vast majority of these Schedule 2 drugs as illustrated in Figure 1 below.[52] I understand from counsel that a showing that the majority of these drugs are at issue in this litigation is important because it is evidence relevant to the fact-finder's determination that the Defendants' conduct was a substantial contributing factor in creating the nuisance. As a reminder, the harms I attribute to shipments of prescription opioids includes harms due to the subsequent use of other opioids (*e.g.*, heroin, fentanyl) caused by the shipments.

[51] Butrans is a Schedule 3 drug.

[52] Figure 1 is reproduced from Rosenthal Report, Attachment C. These data are based on IQVIA National Prescription Audit (NPA) retail sales of extended units (*e.g.*, number of pills) of Schedule 2 drugs (plus Butrans) by manufacturers by month. The MME for a pill of each drug is computed based on an MME conversion factor obtained from the CDC times the milligram strength of the pill. I understand that Information on the Defendant status for each manufacturer was provided by counsel.

Figure 1
Defendants' Shipments and Total Shipments
[Source: Rosenthal Report, Attachment C]



B. Shipments Interfered with Public Health, Safety, Peace and Comfort of Members of the Bellwether Communities with Continuing and Long-Lasting Effects

40. The most obvious and consequential negative impact of opioid shipments is death. As discussed by Professor Gruber, more than 47,000 Americans died from an opioid overdose in 2017, a death toll greater than deaths due to guns or to H.I.V. at the peak of its epidemic.[53] The opioid crisis has hit the Bellwether counties particularly hard. Professor Gruber notes that between 2010 and 2016, the opioid mortality rate in Cuyahoga County increased by 280 percent and in Summit County increased by 362 percent, compared to the overall U.S. large

[53] Gruber Report ¶ 7.

county opioid mortality rate of 88 percent.[54] Both Summit and Cuyahoga counties were among the top 7 percent of U.S. counties in terms of opioid mortality rates in 2016.[55]

41. Figure 2 (Figure I.10 from the Gruber Report) shows the rates of shipments of prescription opioids (measured in MMEs per capita per day) in the Bellwether counties. The magnitude and shape of the curves for the Bellwethers showing rates over 2006-2016 are similar to the national trends, all peaking in 2010/11. Figure 3 (Figure I.11 from the Gruber Report) graphs opioid mortality rates for the Bellwether counties and the national average for large counties.[56] Up until the turning point of 2010/11 in the rate of shipments, the death rates nationally for large counties and in the Bellwethers were similar and growing only slowly. After 2010, however, death rates escalated dramatically in both Cuyahoga and Summit counties, vastly outpacing national increases for large counties.

[54] Gruber Report, ¶ 65.

[55] Gruber Report, ¶ 65.

[56] The Gruber Report indicates at ¶ 36 that large counties are those with a population greater than 100,000. He notes at his footnote 48 that "The simple correlation between the national opioid-related mortality rate and the total rate in the large county sample is 0.996."

Figure 2
Shipments of Prescription Opioids: 1997-2016
Bellwether Counties and U.S. Total
[Source: Gruber Report, Figure I.10]

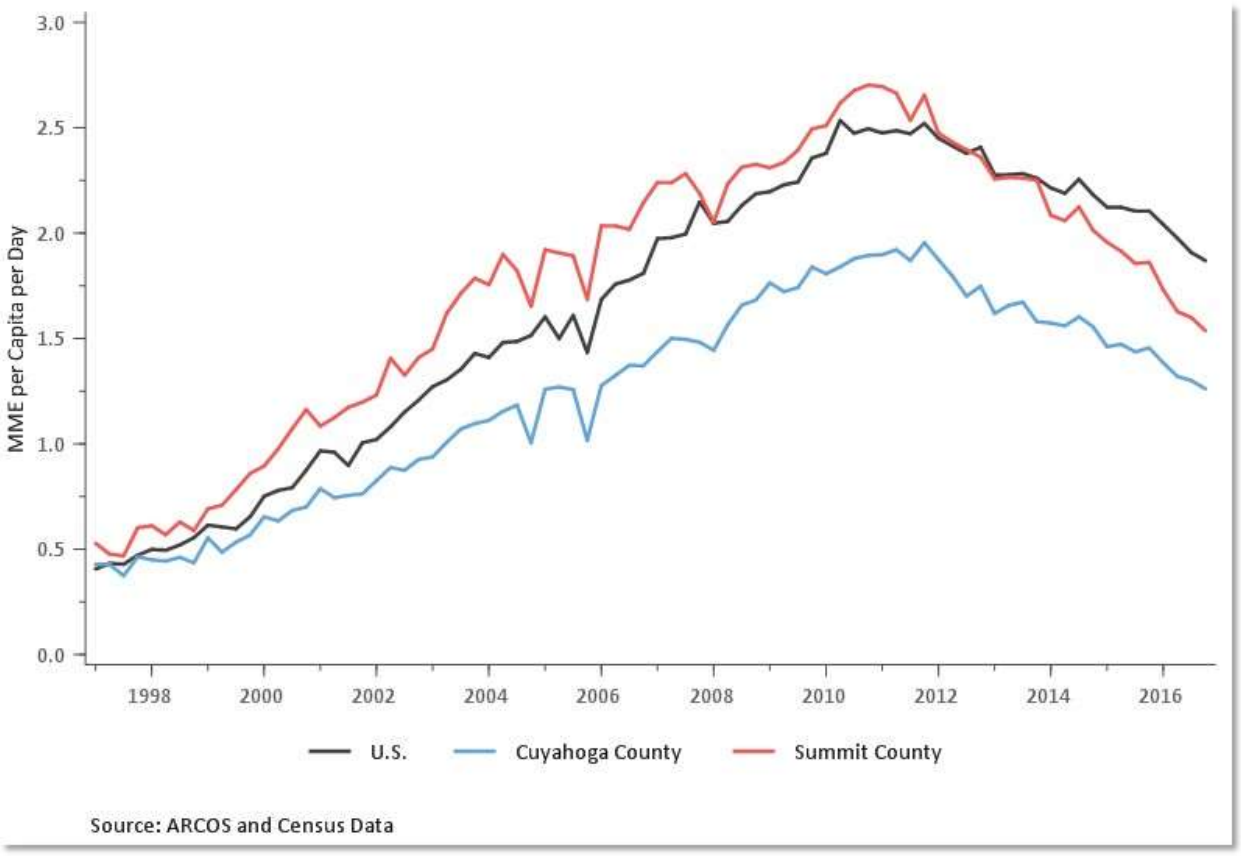
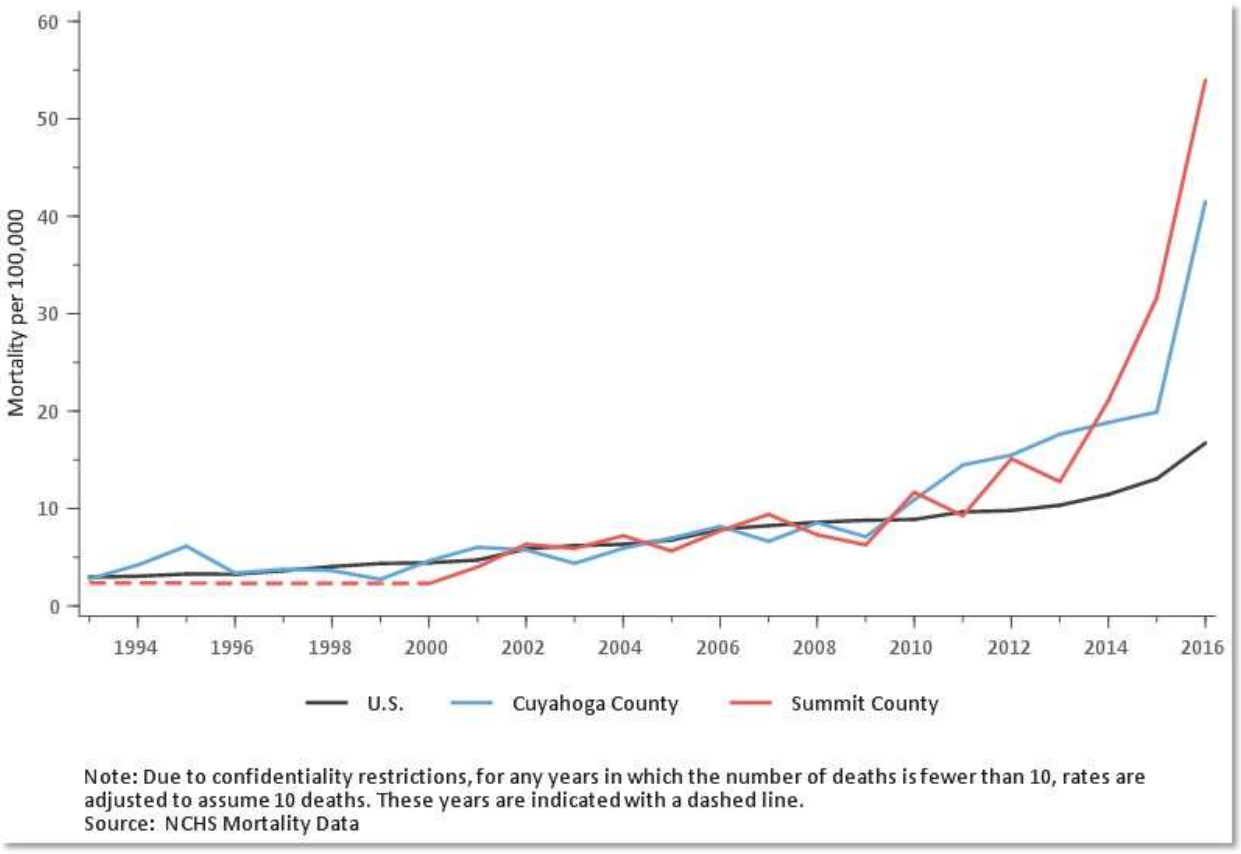


Figure 3
Opioid Mortality Rates: Bellwether Counties v. U.S. Large Counties
[Source: Gruber Report, Figure I.11]



42. Death is not the only negative impact. Professor Cutler empirically assesses the impact of shipments of prescription opioids on three forms of harms: on the rates of mortality, on the rates of crime, and on the number of children needing foster care placement in the Bellwether communities. In this Report, I broaden the scope of harms to children by quantifying child maltreatment (only some of which results in foster care). I also add tallies of the rates of morbidity and of neonatal abstinence syndrome (NAS). I then use the magnitude of these five harms (mortality, morbidity, crime, child maltreatment and NAS) to establish the existence of

significant long-term negative effects of shipments on the public health, safety and peace of members of the Bellwether communities.[57] Later, in Section IV of this Report, I value these harms in dollars.[58] These five are not the only forms of harm associated with shipments; these five are, however, sufficient in my view to establish the existence of widespread and ongoing interference to public health and welfare from the Defendants' opioid shipments. In the remainder of this section, I discuss my methods for quantifying the five harms on which I focus in this Report.

Mortality

43. Professor Cutler applied two empirical approaches to estimate the opioid-related mortality attributable to opioid shipments. His Approach 1 uses the results of a "direct" regression model that estimates the relationship between changes in opioid-related mortality and shipments of prescription opioids between 1995-2010, while controlling for other key variables likely to explain the growth in mortality over that time period. He uses this regression model to estimate the share of mortality attributable to shipments for all opioids through 2010 and the share of mortality attributable to prescription opioids only for 2011-2016. This is combined with an "indirect" regression model that estimates the illicit opioid mortality that is

[57] Professor Cutler estimated the share of studied harms due to Defendants' misconduct by multiplying Professor Rosenthal's estimated share of shipments due to misconduct by his own estimate of the share of harms due to shipments. In this Report, I assess the external costs associated with prescription shipments without regard as to whether they were due to Defendants' misconduct. I thus use the share of harms due to shipments without multiplying by Professor Rosenthal's estimate of the share of shipments due to misconduct.

[58] Professor Cutler was concerned with the impact of prescription opioid shipments on Bellwether governments, so therefore did not address some harmful effects of these shipments, such as mortality costs not falling on Bellwether governments, the cost of crime to victims, lost productivity, and other categories of harm that will be considered here.

attributable to shipments from 2011 through 2016. This second regression model estimates the relationship between illicit opioid mortality and the economic and demographic characteristics of counties over the 2008-2010 period, yielding an estimate of illicit opioid mortality rates for 2011-2016 that would have been expected to prevail in the absence of the reformulation of OxyContin and the reduction in opioid shipments. Combining these two regression models gives Professor Cutler the full effect of shipments on mortality due to licit and illicit opioids over the full time period, 1995 through 2016.[59]

44. His Approach 2 calculates the share of opioid mortality due to shipments based on an indirect regression model that estimates the relationship between opioid mortality and the economic and demographic characteristics of counties similar to Cuyahoga and Summit over the 1993 to 1995 period. This analysis is based on the period before the launch of OxyContin and the subsequent acceleration in the growth of prescription opioid shipments, and thus yields estimates of opioid mortality rates that would have been expected to prevail in the absence of these events. Professor Cutler uses this method to calculate a second estimate of the percent of opioid mortality that is attributable to shipments for 2006 through 2016.[60]

45. Professor Cutler's Approach 1 and Approach 2 lead to broadly similar quantitative estimates of the effect of shipments on mortality. In the text of this Report, I focus on Professor Cutler's results from his Approach 1 which yields more conservative calculations as inputs for my analysis. This choice is not meant as a comment on the appropriateness of

[59] For more details on Professor Cutler's Approach 1, see Cutler Report, Section VI.A.

[60] For more details on Professor Cutler's Approach 2 see Cutler Report, Section VI.B. Also see Cutler Report, Appendix III.I, Tables I.4 and I.5 for Professor Cutler's estimates of harms attributable to all shipments.

Approach 1 over Approach 2 but is simply done for ease of discussion in the text of this Report. Although the dollar amounts attributable to my conclusions of the public nuisance calculations undertaken here change depending on which of the approaches I use, my other conclusions do not change based on the approach chosen. For completeness, I repeat my analysis presented in the body of this Report, in Appendix I, using Approach 2.

46. I apply Professor Cutler's estimates of the share of opioid-related mortality due to shipments to the death rate in each county in each year to determine the absolute numbers of deaths each year attributable to shipments in Cuyahoga and Summit counties.[61] Over the entire 11-year period from 2006-2016, 2,158 deaths in the Bellwether counties can be attributed to opioid shipments.[62] I emphasize that these are not just opioid-related deaths; these are, based on Professor Cutler's findings, opioid-related deaths *attributable to Defendants' shipments* of prescription opioids.

47. These shipment-related deaths can be put in perspective by comparing them to the number of deaths from firearms in each year in each county.[63] In broad terms, the number of

[61] Mortality data are based on the Multiple Cause of Death (MCOD) files published by the National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention (CDC). See https://www.cdc.gov/nchs/index.htm. These data are generated from death certificates and report mortality by cause of death and by county of residence. A single death may have multiple causes. Opioid overdose deaths have an underlying cause of death code related to drug poisoning and one or more additional codes related to opioids. Because some overdose fatalities fail to identify the underlying drug associated with the death, these numbers are conservative. Note that in the Cutler Report, these numbers are adjusted by following the procedures outlined in Ruhm (2018) to allocate these unidentified drug overdoses as either opioid-related or non-opioid related (See C.J. Ruhm, "Corrected US Opioid-Involved Drug Poisoning Deaths and Mortality Rates, 1999–2015," *Addiction*, 113, 2018, pp. 1339-1344).

[62] See Tables 5a and 5b in Section IV of this Report for a summary by year of deaths due to prescription opioid shipments. See Appendix C for a discussion of the data sources and calculation methods.

[63] Firearm-related deaths are downloaded from CDC's Wonder data tool and are based on the same underlying MCOD data as opioid mortality. Cause of death codes to identify firearm-related deaths are based on Xu *et al.* (2018) (J. Xu, *et al.*, "Deaths: Final Data for 2016," *National Vital Statistics Reports*, 67(5), July 26, 2018).

people killed by opioid shipments over this period was roughly the same as those killed by guns.[64] By 2016, however, shipments were killing over twice as many people as guns in Cuyahoga County and more than three times as many people as guns in Summit County.[65]

Morbidity

48. In addition to the public harms from deaths due to opioid shipments, harms result from opioid-related morbidity. Morbidity simply means to have a disease or be in ill health. Opioid use disorder (OUD) is a substance use disorder that is diagnosed by health care providers using specific assessment criteria from the Diagnostic and Statistical Manual of Mental Health Disorders.[66] Individuals with OUD are at a high risk of death. OUD is a chronic disease, meaning once ill with OUD, a person may remain ill for years.[67] According to the CDC, there were 2.1 million Americans with OUD as of 2016.[68] The disorder is defined as a "problematic pattern of opioid use leading to clinically significant impairment or distress,"[69] and is diagnosed

[64] There were 1,772 deaths due to firearms in Cuyahoga County from 2006 through 2016 and 2,114 deaths due to opioid shipments. In Summit County, there were 604 deaths due to firearms and 804 deaths due to opioid shipments. See Centers for Disease Control and Prevention (CDC), Wonder data for data on deaths by firearms by County (available at https://wonder.cdc.gov/controller/datarequest/D77).

[65] *Ibid.*, In 2016 there were 235 firearm deaths in Cuyahoga County and 68 in Summit County compared to 504 deaths due to opioid shipments in Cuyahoga County and 269 in Summit County.

[66] Substance-Related and Addictive Disorders in: American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders,* 5th edition, DSM Library. Arlington, VA, 2013.

[67] National Institute on Drug Abuse, Addiction is a Chronic Disease, available at https://archives.drugabuse.gov/publications/drug-abuse-addiction-one-americas-most-challenging-public-health-problems/addiction-chronic-disease.

[68] CDC, Module 5: Assessing and Addressing Opioid Use Disorder (OUD), available at https://www.cdc.gov/drugoverdose/training/oud/accessible/index.html.

[69] Substance-Related and Addictive Disorders, *op. cit.*

by evaluating patients for at least two of 11 clinical symptoms within a 12-month period.[70] "OUD exists on a continuum of severity … based upon the number of criteria that have been met."[71]

49. Determining the morbidity in the Bellwether counties due to shipments of prescription opioids proceeds in two steps. I first estimate the overall prevalence of OUD in the Bellwether counties for 2006 through 2016, and second, I estimate the share of this morbidity attributable to shipments. The product of these two yields the number of OUD cases in each county for each year attributable to shipments.

50. For the first of these two steps, I begin with data from the National Survey on Drug Use and Health (NSDUH). I summarize how these data are used and adjusted, and provide a detailed description of data and methods to estimate morbidity rates in Appendix D. Based on the adjusted prevalence rates, I estimate number of persons in each year with OUD based on each of the Bellwether county populations. Tables 7a and 7b in Section IV below report the prevalence of disease in each year.

51. In the second step needed to estimate disease prevalence due to shipments, I rely on Professor Cutler's finding about the share of opioid-related *mortality* attributable to shipments

[70] Examples of these symptoms include taking opioids in larger amounts or over a longer time period than was intended, being unsuccessful in efforts to reduce or control opioid use and having cravings or strong urges to use opioids. For all twelve symptoms, see CDC, Module 5: Assessing and Addressing Opioid Use Disorder (OUD), available at https://www.cdc.gov/drugoverdose/training/oud/accessible/index.html.

[71] *Ibid*.. The previous edition of the Diagnostic and Statistical Manual from 1994 did not include opioid use disorder as a diagnosis; rather, it contained two separate diagnoses, opioid dependence and opioid abuse. *Diagnostic and Statistical Manual of Mental Disorders,* 4th ed. Washington, DC: American Psychiatric Association; 1994. These were combined into a single disorder in 2013. D.S. Hasin, *et al.*, DSM-5 criteria for substance use disorders: recommendations and rationale, *American Journal of Psychiatry,* 2013, 170(8), pp. 834-851.

and assume that the same share applies to *morbidity.*[72] These shares are shown in Tables 7a and 7b (and are the same as the shares I use in the mortality analysis). Multiplying the number of persons with OUD in each year by the share attributable to shipments provides the absolute number of people in each county with disease attributable to shipments in each year. As identified in Tables 7a and 7b below in Section IV, over the 11-year period from 2006-2016, there were approximately 109 thousand person-years of opioid-related morbidity due to shipments in Cuyahoga County and approximately 46 thousand person-years of opioid-related morbidity due to shipments in Summit County.

Babies born with neonatal abstinence syndrome

52. Neonatal abstinence syndrome (NAS), also termed neonatal withdrawal,[73] is a constellation of conditions associated with *in utero* exposure to opioids.[74] It can occur due to any regular antenatal opioid use, including both illicit and prescribed.[75] The syndrome is a rapidly growing public health problem, with the incidence of NAS increasing nearly fivefold between 2000-2012, corresponding with a rise in opioid use and abuse.[76] Babies born with NAS

[72] Professor Cutler states in his report that "opioid-related mortality is used as a proxy for opioid-related harms" (¶ 27). He explains why mortality is a good proxy for harms in his ¶48.

[73] K. McQueen and J. Murphy-Oikonen, "Neonatal abstinence syndrome," *New England Journal of Medicine,* 2016, 375(25), pp. 2468-2479.

[74] H. Uebel, *et al.*, "Reasons for Rehospitalization in Children who had Neonatal Abstinence Syndrome," *Pediatrics, 2015,* 136(4), e811-e820.

[75] S. Wong, *et al.*, "Substance use in pregnancy," *Journal of Obstetrics and Gynaecology Canada*, 2011, 33(4), pp. 367-384.

[76] S.W. Patrick, *et al*., "Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009," *JAMA,* 2012, 307(18), pp. 1934-1940; S.W. Patrick, *et al.*, "Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012," *Journal of Perinatology*, August 2015, 35(8), pp. 650-655.

may exhibit a host of symptoms, including respiratory distress; central nervous-system symptoms, like tremors and seizure; and gastrointestinal problems, such as poor feeding and vomiting.[77] The onset of symptoms typically occurs within the first few days following birth, but timing may vary due to a variety of factors, including the half-life of the specific opiate used.[78] In this section, I describe the methodology for estimating the number of NAS cases in the Bellwether counties attributable to opioid shipments.

53. According to the Ohio Department of Health, virtually all cases of NAS are due to opioids.[79] I use publicly available on the number of NAS cases by county of residence within Ohio over the period from 2006-2016 (see Appendix E for details). Tables 8a and 8b in Section IV below report the number of NAS cases for each year between 2006-2016. I then multiply these estimates by Professor Cutler's estimates of the share of harm attributable to shipments to arrive at a number of opioid-related NAS cases *attributable to the shipments*. As reported in Tables 8a and 8b, between 2006-2016, I estimate that there were 609 cases of opioid-related NAS attributable to shipments in Cuyahoga County, and 430 cases attributable to shipments in

[77] Wong et al., op. cit.

[78] Wong et al., op. cit.

[79] See Ohio Department of Health, "Neonatal Abstinence Syndrome (NAS) Hospital Reporting in Ohio, July 2, 2018, available at https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/resources/nas_hospital_reporting_in_ohio. Also see "2017 Ohio Neonatal Abstinence Syndrome County Report," available at https://odh.ohio.gov/wps/wcm/connect/gov/4cad708c-ba99-4b8b-b425-01cfef119c5d/2017+NAS+County+Table+12.3.2018.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE.Z18_M1HGGIK0N0JO00QO9DDDDM3000-4cad708c-ba99-4b8b-b425-01cfef119c5d-muueFzr.

Summit County.

Crime

54. The opioid crisis could increase the number of crimes committed in the Bellwether communities in several ways. For example, the sale of illegal opioids (*e.g.*, heroin) for any use or prescription opioids (*e.g.*, OxyContin) for illicit use is a crime. Additionally, people misusing opioids may commit crimes, such as property theft, to obtain money to buy opioids or their drug use may lead to other crimes, such as assault.

55. Appendix F contains the details on how I estimate the number of crimes due to opioid shipments and the economic costs of those crimes. In sum, I start with a count of the total number of crimes in different categories, (*e.g.*, motor vehicle theft, prostitution, vandalism) committed within the Bellwether communities. Counts of incidents within each Bellwether community come from the National Incident-Based Reporting System (NIBRS) maintained by the FBI. NIBRS data are a standard source used to measure criminal offenses by criminal category for all law enforcement agencies (LEAs) that report into NIBRS. Not all LEAs report their data to the NIBRS.[80] I then apply methods from Professor Cutler's report to determine the share of these crimes attributable to shipments. As described in his Section IV.A and summarized in my Appendix F, Professor Cutler uses data from a number of sources to make this attribution.

[80] The Bureau of Justice Statistics reported that, "In 2012 NIBRS-contributing agencies served approximately 30 percent of the U.S. population and accounted for 28 percent of all crime reported to the UCR [Uniform Crime Reporting] Program." See Bureau of Justice Statistics, Data Collection: National Incident-Based Reporting System (NIBRS), available at https://www.bjs.gov/index.cfm?ty=dcdetail&iid=301.

56. Tables 9a and 9b in Section IV below summarize results for the two counties, showing the impact in terms of incidents of crime on each community for each year, 2006 – 2016. Over the time period from 2006-2016, there were over almost 44 thousand crimes in Cuyahoga County and almost 21 thousand in Summit County due to shipments. These numbers are conservative given the reporting limitations in the NIBRS identified above.

Child maltreatment

57. Substance abuse, including opioid abuse, is a major cause of child maltreatment.[81] According to the U.S. Department of Health and Human Services (2019), nearly 700,000 children are subject to maltreatment (includes abuse and neglect) each year in the U.S., with the majority of cases involving neglect (74.9%).[82] In Ohio in 2017, 24,897 cases of maltreatment were substantiated or indicated; of these, more than half involved a caregiver with a substance use risk factor.[83]

58. I rely on Dr. Young for the number of unique children subject to maltreatment in the Bellwether counties.[84] I use data from the Cutler Report to estimate the share of maltreated

[81] See U.S. Department of Health & Human Services, Administration for Children and Families, Administration on Children, Youth and Families, Children's Bureau, "Child Maltreatment 2017,"; 2019, available at https://www.acf.hhs.gov/sites/default/files/cb/cm2017.pdf; O. Mowbray, *et al*., "Longitudinal Trends in Substance Use and Mental Health Service Needs in Child Welfare," *Children and Youth Services Review,* 73, 2017, pp. 1-8..

[82] *Ibid.*, p. ii; J.J. Doyle and A. Aizer, "Economics of Child Protection: Maltreatment, Foster Care, and Intimate Partner Violence," *Annual Review of Economics*, 2018, 10, pp. 87-108.

[83] Broken down by type of maltreatment (categories not mutually exclusive): neglect: 11,212; medical neglect: 493; physical abuse: 11,892; psychological maltreatment: 914; sexual abuse: 4,339. See U.S. Dep. Health Hum. Serv. 2019. This is likely to be an underestimate, since it relies on reports to Child Protective Services agencies. Victimization surveys and other sources report higher rates of maltreatment. See F. Wulczyn, "Epidemiological Perspectives on Maltreatment Prevention," *The Future of Children*, Fall 2009, 19(2), pp. 39-66; and Doyle & Aizer *op. cit.*

[84] See Young Report, Graphics 12 and 13.

children due to opioids. I then apply Professor Cutler's estimate of the share of opioid-related harms due to shipments to obtain estimates of the number of children maltreated due to shipments. These results are reported in Tables 10a and 10b in Section IV for Cuyahoga and Summit Counties, respectively. Over the period 2006-2016, shipments of prescription opioids caused 1,391 cases of maltreatment in Cuyahoga County and 1,031 cases of maltreatment in Summit County. Appendix G contains details of the calculations.

Summary

59. Harms *caused by shipments of prescription opioids* to the Bellwether communities over 2006 - 2016 quantified in this section are summarized in Table 2.[85]

Table 2
Summary of Harms Due to Opioid Shipments
2006-2016

Harm	Cuyahoga	Summit
Excess deaths	1,535	623
Excess morbidity	108,515	46,183
Excess neonatal abstinence syndrome	609	430
Excess crimes	43,957	20,779
Excess child maltreatment	1,391	1,031

Sources: Tables 5a, 5b, 7a, 7b, 8a, 8b, 9a, 9b, 10a and 10b of this Report.

[85] Note that this is not an exhaustive list of harms.

60. I conclude that shipments of prescription opioids significantly interfered with public health, safety, peace and comfort of the members of the Bellwether communities with continuing and long-lasting effects.

C. The Interference from Shipments was Unreasonable

61. I consider the question of whether the shipments of prescription opioids were reasonable or unreasonable from two perspectives. The first perspective considers whether the shipments were reasonable from the standpoint of being used for clinically justified treatment. The second perspective considers whether the shipments were reasonable from the standpoint of economic costs and benefits.

Share of shipments for scientifically acceptable treatment

62. I have been instructed by counsel to assume that the Court will conclude that, under applicable public nuisance law and in the context of a prescription medication, the meaning of "unreasonable" is, in substance, "not justified by clinical need." In other words, a "reasonable" shipment of opioids would be to treat a patient in accordance with scientifically acceptable medical criteria. Shipments not for such a purpose are not reasonable.

63. Using epidemiological data and medical opinions about scientifically acceptable uses, treatments and dosages for opioids, Professor Rosenthal has calculated a theoretical maximum for quantities of prescription opioids (measured in MMEs) for three patient groups needing treatment for pain.[86] She cites professional academic articles as well as relying upon Dr. Schumacher and Dr. Parran in her selection of end-of-life cancer patients, trauma patients and

[86] Rosenthal Report, Section X.

surgery patients as those patient groups appropriately treated by opioids. Professor Rosenthal also relies on some of the same sources to identify the average dosage level and treatment durations that are appropriate for these patient groups.

64. I have been advised by counsel that Dr. Schumacher will testify that at most, opioids are properly indicated for the short-term treatment of severe acute pain (e.g., trauma or post-surgical pain); end-of-life pain/hospice care; and cancer pain from active malignant disease. Chronic opioid therapy is not recommended for most common chronic pain conditions, including low back pain, centralized pain such as fibromyalgia, and headache pain. In less common chronic pain conditions (such as pain from advanced multiple sclerosis, sickle cell disease, pain following spinal cord injury and paraplegia, or post-herpetic neuralgia), which comprise a small percentage of chronic pain patients, opioids may be considered a third-line therapy (taken if other therapies are ineffective or contraindicated) for moderate and severe pain. However, in other neurologic conditions such as polyneuropathy, no functional status markers were improved by long-term use of opioids, adverse outcomes were more common among patients with polyneuropathy receiving long-term opioids, including depression opioid dependence and opioid overdose. In addition to diagnosis, clinicians should consider risk, and some patients may not be suitable candidates on the basis of that risk. Given the narrow categories that may indicate opioids for chronic use, opioids' position as third-line therapy, and the significant risks associated with its use, long-term opioid therapy for persons with chronic pain conditions is, at most, indicated in fewer than 5% of patients with chronic pain and likely significantly fewer. For all proper indications other than terminal cancer, palliative care and

hospice care, if prescribed, opioids should be prescribed with the lowest effective dose of immediate-release opioids taken only when needed.

65. These clinical positions are consistent with criteria employed by Professor Rosenthal in addressing scientifically acceptable use of prescription oral opioids.[87] See also the Report of Dr. Parran.

66. Professor Rosenthal produces national estimates for the theoretical maximum, scientifically acceptable use over the period 1993 to the present and finds the maximum justifiable share to be no more than 10% in every year from 2006-2016 of the actual observed MMEs of opioid prescriptions.[88] In addition to her national analysis, Professor Rosenthal conducts a similar analysis for the Bellwether communities.[89] The number of cancer deaths in the Bellwether communities are estimated from state-wide mortality rates available from US Cancer Statistics, Centers for Disease Control (CDC). State-wide incident rates are multiplied by county population to estimate Bellwether cancer mortality by year. The number of inpatient and outpatient surgeries are obtained from the American Hospital Resource File (AHRF). The number of Bellwether trauma cases are estimated based on Health Care Utilization Project (HCUP) data from the Agency on Healthcare Research and Quality (AHRQ) by multiplying the national-wide emergency room visits by Bellwether population. The theoretical maximum clinically justified usage for each of the patient groups is found by multiplying the number of cases by the appropriate average daily MME and treatment duration.

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[87] Rosenthal Report, ¶ 92-94.

[88] See Rosenthal Report, Table 6, last column.

[89] The details supporting the following calculations are provided in Rosenthal Report, ¶ 100 and Table 7.

67. The estimates of total appropriate use of opioids for the Bellwether communities for 2006-2016 are contained in Table 7 of the Rosenthal Report. The Table also shows the total actual shipments into the Bellwether communities. As shown in Rosenthal Table 7 the share of opioid shipments which were clinically justified ranges from 13.1% to 19.6% of actual shipments in Cuyahoga from 2006 through 2016 and from 6.5% to 10.0% in Summit.

68. As Professor Rosenthal explains, because every patient in these appropriate treatment groups would not have been treated with opioids, the shares of potentially appropriate shipments are overestimates of the shares of shipments that were actually directed to appropriate treatment.[90]

69. The low share of shipments being appropriate is confirmed by an analysis conducted by Professor Gruber, where he found that demographic factors like age, that are correlated with disease prevalence, explain little of the cross-sectional variation in shipments.[91] He observes "The extreme variation in per capita shipments across areas suggest that prescription activity, which drives shipments to an area, bears little relationship to medical need."[92]

70. Using the criterion that a reasonable shipment is one for an appropriate medical need and an unreasonable shipment was one for some other purpose, results in Rosenthal Table 7 indicate that the vast majority – at least 80% in Cuyahoga and at least 90% in Summit – of

[90] Rosenthal Report, ¶ 94-101.

[91] Gruber Report, Section IV A.

[92] Gruber Report, ¶ 74.

shipments to the Bellwether communities over this period were not justified by clinical need and were therefore unreasonable.[93]

Benefits and costs

71. When used according to scientific criteria, prescription opioids reduce pain for some users and may increase the user's ability to work. As I show here, however, the magnitude of these beneficial effects is dwarfed by the harmful effects. Thus, I also find that shipments of prescription opioids are also unreasonable from the standpoint of benefits and costs.

72. In this analysis I ignore costs of production, distribution, marketing, product development and any other cost of production of shipments. The costs I assess here are only the harmful effects on users of prescription opioids. Including consideration of conventional costs of production by manufacturers and distributors would increase the extent to which costs exceed benefits of shipments.

73. *Workforce participation and productivity.* Pain interferes with an individual's ability to work,[94] and appropriate treatment of pain enables some to work who would have otherwise been prevented from working due to pain.[95] A study of the effects of Cox-2 inhibitors (non-

[93] Professor Rosenthal conducts sensitivity analyses to allow for the possibility that some other patients would also be appropriately treated with opioids. She discusses this in her ¶101 and concludes that potential modifications of the clinical groups are captured in her sensitivity analyses.

[94] D.J. Gaskin and P. Richard, "The Economic Cost of Pain in the United States," *The Journal of Pain*, 13(8), 2012, pp. 715-724.

[95] Participation in the labor force benefits the individual and the wider society. The individual benefits to the degree that added income adds to their consumption opportunities. Others benefit to the degree that the added income of the worker increases public tax revenue or offsets costs others would have paid to support consumption of the individual had they been out of the labor force. For example, if someone out of the labor force is paid unemployment or disability benefits, avoiding these transfer payments benefits the public. Support for an individual out of the labor force may come from other family members, and this support is not needed if an

opioid pain medications) finds that treatment increases workplace attendance.[96] Likewise, prescription opioids, when used appropriately for treatment of pain, may increase labor force participation and employment for pain-afflicted individuals. According to one study, the introduction of state Prescription Drug Monitoring Programs (PDMPs), intended to address prescription drug diversion and abuse, led to decreases in opioid prescriptions and increases in absence rates for short-term disabled and injured workers.[97]

74. Prescription opioids, when used inappropriately, however, can lead to death, morbidity, crime, incarceration, and child maltreatment, all of which decrease labor force participation of the user and/or of others in the immediate and longer term. A paper from the Workers Compensation Research Institute studied the effect of opioid prescriptions on workers out on temporary disability with low-back pain. Long-term treatment with opioids increased the length of time workers missed work.[98]

75. Some recent papers in the economics literature study the effect of opioid prescriptions on a geographic basis (rather than for populations who might benefit from appropriate treatment), and thus capture empirically both the short-term positive effects (from appropriate

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individual is working and supporting themselves. In other words, how much of the benefits of labor force participation flow directly to the worker or are external to others depends on the individual circumstances.

[96] Cox-2 inhibitors are not generally used for recreational purposes. See C. Garthwaite, "The economic benefits of pharmaceutical innovations: The case of cox-2 inhibitors," *American Economic Journal: Applied Economics*, 2012, 4(3), pp. 116–137. A. Butikofer and M. M. Skira, "Missing Work is a Pain: The Effect of Cox-2 Inhibitors on Sickness Absence and Disability Pension Receipt," *Journal of Human Resources*, 2018, 53(1), pp. 71-122.

[97] A.E. Kilby, "Opioids for the masses: Welfare tradeoffs in the regulation of narcotic pain medications," 2015, Working Paper, Northeastern University. Decreases in prescriptions may have moved users to dangerous illicit drugs, explaining the increase in absentee rates.

[98] B. Savych, D. Neumark and R. Lea, (2018), "The Impact of Opioid Prescriptions on the Duration of Temporary Disability," Workers Compensation Research Institute, Cambridge, MA, March.

pain treatment) and some negative effects (from inappropriate treatment) of opioid prescriptions on work. As one of pair of authors put it, "Because it is impossible to distinguish between legitimate and illegitimate uses of prescription opioids, we interpret these [geographic-level] results as a net effect of both types of use."[99] These authors found that the net effect at the state level was negative.[100] One paper using county data on prescription rates and employment by age and gender finds that a higher rate of prescriptions has a small positive effect on employment for women, but no effect on men.[101] Another paper found that areas with higher opioid prescription rates have lower rates of labor force participation overall.[102] Finally, a very recent paper finds that increasing shipments of prescription opioids decreases the prime-age employment rate for both men and women.[103]

76. Overall, on the basis of the available evidence I am of the opinion that the short-term effect of shipments on work results in a negative relationship: more shipments means less

[99] M.C. Harris, L.M. Kesslery, M.N. Murray and M. E. Glenn (2019). "Prescription opioids and labor market pains," forthcoming, *Journal of Human Resources*, pages 3-4 in web version.

[100] Harris *et al.* (2019) *op. cit.* study ten states using data from Prescription Drug Monitoring Programs and find that a 10% increase in prescriptions leads to a .56% decrease in labor force participation.

[101] J. Currie, J. Jin and M. Schnell, "U.S. Employment and Opioids, Is there a Connection?" NBER Working Paper 24440, March 2018.

[102] A. Krueger, "Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate," Brookings Papers on Economic Activity, 2017.

[103] D. Aliprantis, K. Fee and M.E. Schweitzer (2019), "Opioids and the Labor Market," Federal Reserve Bank of Cleveland, Working Paper no. 18-07.

work. Furthermore, these studies, focusing on the contemporaneous and short-term effect of prescriptions underestimate the negative effects which play out over time.

77. These short-term effects are not alone. As Professor Cutler shows and as I agree, the harmful effects of prescriptions today continue for years. These longer-term harmful effects likely apply to work-related disabilities as well. And finally, other channels by which opioid shipments have negative effects on productivity over time – deaths after transition to street drugs, crime and incarceration, maltreatment that affects a child's income as an adult -- are not captured in the contemporaneous correlation of shipments and productivity.[104] Deaths are a clear example of the delayed negative impact of shipments. As Professor Cutler shows, deaths today are caused by shipments years ago.[105] I have not undertaken a quantification of the longer-term effects on productivity from shipments (apart from death, criminality, and child maltreatment). But given the dynamics of opioid use and OUD, measurement of these longer-term effects on productivity from shipments would result in a much greater imbalance where the costs far exceed the benefits to productivity.

78. The overall purpose of my analysis here is to determine whether overall costs from shipments exceed ostensible benefits. As a result, if a particular quantification is not needed to make that determination, I can simplify the analysis by making conservative assumptions.

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[104] Empirical research shows that the effects through these other channels swamp any possible small net positive from appropriate pain treatment (after subtracting short-term negative effects from higher rates of morbidity). For example, Florence *et al*. (2016) estimate the value of lost productivity from disease ("non-fatal costs") to be $16.3 billion. These are the negative effects possibly offset by positive effects of pain relief. The value of lost productivity from deaths ("fatality costs") and incarceration were estimated at $21.4 and $4.2 billion, respectively. C. Florence, *et al.*, "The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013," *Medical Care*, October 2016; 54 (10), pp. 901-906. This analysis attributes disease rates to prescriptions based on specific questions in the NSDUH.

[105] Cutler Report, ¶ 68 where he notes shipments may have "long-term" effects.

Therefore, when counting and valuing the effects of shipments on productivity, I will very conservatively treat the positive and negative short-term effects of shipments approximately cancel out, leaving the long-term negative effects as the net productivity effect of shipments. Specifically, any arguable short-term positive effects on productivity from pain relief are more than offset by losses due to the contemporaneous presence of disease. When tallying the net effect of shipments on productivity, I will not count lost productivity from morbidity (present in the short term), but I will count lost productivity to effects occurring over a longer term, due to death,[106] criminal careers, and child maltreatment.[107]

79. *Quality of life.* Shipments of prescription opioids can affect a user's quality of life. Opioids are clinically justified analgesics for some categories of patients. Reducing pain improves a patient's quality of life. On the other hand, shipments of prescription opioids put users and others at risk for OUD and its *sequelae*. These diseases reduce affected individuals' quality of life.

80. Data on the prevalence of patients who are candidates for treatment with opioids and on the prevalence of OUD (and its relation to shipments) permits a comparison of positive and negative effects of opioid shipments on quality of life. I use the same sources as Professor Rosenthal to count the number of cancer deaths, surgeries and trauma cases in the Bellwether

[106] As I explain below in Section IV.D., lost productivity is included within the "value of a statistical life" used to figure the economic cost of a death. Therefore, I make no separate accounting here for productivity lost associated with mortality.

[107] In the short-term effects, more work due to pain treatment is likely to come from clinically appropriate use whereas the short-term interference with work due to higher rates of OUD is likely to come from clinically inappropriate use. Allowing the short-term positive effects to balance out the short-term negative effects does not change the fact that by causing disease, shipments have elevated rates of OUD and interfered with work.

communities for 2014, the most recent year for which data are available.[108] Professor Rosenthal also reports estimates of the appropriate duration of pain treatment for these individuals, of 64 days (on average) for people dying of cancer and 7 days on average for cases of surgery or trauma.[109] Combining the number of cases with the average duration of treatment yields a maximum theoretical number of days that shipments of opioids might alleviate pain. In both Cuyahoga and Summit counties, the number of days residents of the counties suffer from the presence of OUD (ignoring for this calculation *sequelae* such as HIV and Hepatitis C) vastly outweighs the maximum potential days of clinically justified pain relief. Specifically, for 2014 in Cuyahoga, days living with disease outweigh days with pain relief by a ratio of 1.8 to 1; in Summit, the ratio is 2.8 to 1.[110]

81. These ratios significantly underestimate the ratio of harms to benefits. Regarding the numerator of the ratio (harms), NSDUH, the source of estimates of the prevalence of OUD, undercounts the number of individuals suffering from OUD.[111] Regarding the denominator

[108] These are listed above in ¶66. See Rosenthal Report, Section X. and Table 7.

[109] For average duration of treatment for cancer palliative care, Dr. Rosenthal uses a number below the average number of days patients spend in hospice (see Rosenthal Report, ¶ 96 and footnote 134). For trauma and post surgery, Dr. Rosenthal uses seven days. (see Rosenthal Report, ¶¶ 98 and 99 and footnotes 137, 138 and 141).

[110] The number of days with OUD for 2014 come from Appendix D Tables D.3a and D.3b (also see Tables 7a and 7b below) reporting estimates of OUD due to shipment based on Professor Cutler's Approach 1 (Approach 2 yields higher estimates). The number of people with OUD is 13,400 for Cuyahoga and 5,800 for Summit, corresponding to days 365*13,400 and 365*5,800 for the counties, respectively. The maximum number of days of potential pain relief is found by multiplying the number of cases for each of the three conditions times the average duration of treatment, 64 days for cancer and 7 days for the other two conditions. For Cuyahoga the number of cases are cancer deaths 2,998, trauma cases 285,338 and surgeries 84,318. For Summit the number of cases are cancer deaths 1,269, trauma cases 58,246 and surgeries 36,271. The ratio in the text for Cuyahoga is calculated by evaluating [13,400*365/(2,998*64 + 285,338*7 + 84,318*7)] = 1.8. A similar operation is conducted for Summit to yield the ratio of 2.8. See Rosenthal Report for numbers of cases of cancer deaths, trauma and surgeries by county (Rosenthal Report, Attachment D, table titled Epidemiological Data Used for Appropriate Use Analysis).

[111] See Appendix D for more discussion of the NSHUH estimates.

(benefits), the theoretical maximum of the number of patients appropriately treated is likely much higher than those who were actually appropriately treated. Not all patients who could benefit from pain treatment receive it. Of those who would benefit from treatment, opioids are often not the best choice. To illustrate the effect of taking into account of these factors on the ratios presented above, if 20% of patients who may benefit from appropriate treatment do not receive any treatment, and of those who receive treatment, 50% use opioids, the ratio of harms to benefits measured in days affected rise to 4.5 to 1 for Cuyahoga and 7.0 to 1 for Summit.[112] These more realistic ratios emerge correcting only the denominator for its overcount of days of benefit, and not the numerator for its undercount of the days of harm. Correcting the numerator (to account for its underestimation of the prevalence of OUD) would add harm-days and increase the ratio further.

82. As previously mentioned, the scientifically acceptable uses of prescription opioids are, at most, short-term treatment of severe acute pain, end-of-life pain/hospice care, cancer pain from active malignant disease, and a small percentage of the less common chronic pain conditions (such as pain from advanced multiple sclerosis, sickle cell disease, pain following spinal cord injury and paraplegia, or post-herpetic neuralgia) where opioids may be considered a third-line therapy (taken if other therapies are ineffective or contraindicated) for moderate and severe pain. Including these less common chronic pain patients for whom opioids are considered a third-line treatment would not materially change the magnitude of the ratios of

[112] The effect of assumptions that 20% are untreated and 50% of those treated are treated by opioids reduces the number of days with benefits from opioids to 40% of the previous amount (100%-20%)*(50%). Thus, both ratios go up by a factor of 1/.4 = 2.5. 1.8*2.5 = 4.5 and 2.8*2.5 = 7.0.

harms to benefits. These chronic-pain patients are also subject to risk of addiction. In such cases, the harms of opioid treatment may exceed the benefits.

83. The days-of-harm-to-days-of-benefit ratio could be modified by weighting days according to the relative importance of the harms from OUD and the potential benefits from pain relief. Quality-Adjusted Life Years (QALYs) are one candidate for weighting. QALYs assign a utility weight between 0 (death) and 1 (perfect health) to each year of life living in a certain state of health or illness.[113] QALYs standardize utility into a single index that can be "added up" across people.[114]

84. Nothing is to be gained by a QALY-weighting exercise in this context, however, because the estimates from the literature on the QALY gain from pain treatment[115] are in overlapping ranges as the QALYs lost from living with OUD.[116] Weighting the top and bottom of a ratio by

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[113] There are several ways to derive utility valuations of each health state. One example is the Time-Trade-Off approach, in which survey respondents are asked to select the number of years in perfect health they would choose over a given number of years in their current health state. See P. Dolan, *et al.* "The Time Trade-off Method: Results from a General Population Study," *Health Economics*, 5(2), 1996, pp. 141-154.

[114] See M.C. Weinstein, G. Torrance, and A. McGuire, "QALYs: The Basics," *Value in Health,* 12, 2009, pp. S5-S9.

[115] For estimates of the QALY loss from pain, see S. Wetherington *et al.,* (2014), "Pain Quality of Life as Measured by Utilities," *Pain Medicine* (15):865-870, Table 2. Researchers also use alternative scales for measuring utility of disease states, such as the EQ-5D used by Wetherington et al. Utility weights can be considered relative to a life lived in usual health, which is not 1.0. See N. Luo, *et al.*, "Self-Reported Health Status of the General Adult U.S. Population as Assessed by the EQ-5D and Health Utilities Index," *Medical Care*, 43(11), 2005, pp. 1076-1086. This study uses the EQ-5D method to assign utility weights. Utility weights for conditions for which opioid use would be considered appropriate (i.e., conditions other than chronic pain) tend to be higher than utility weights for chronic pain, representing *less* potential for QALY gains from opioid treatment. See J. Diels *et al.,* "Mapping FACT-P to EQ-5D in a large cross-sectional study of metastatic castration-resistant prostate cancer patients," *Qual Lif Res*, 24, 2015, pp. 591-598; M. Lidgren, *et al*., "Health related quality of life in different states of breast cancer," *Qual Lif Res*, 16, 2007, pp. 1073-1081.

[116] The literature contains a range of estimates for the disease burden associated with OUD. See, for example, J.W. Bray, *et al.*, "Quality of Life as an Outcome of Opioid Use Disorder Treatment: A Systematic Review," *Journal of Substance Abuse Treatment*, 76, 2017, pp. 88-93; M. Chetty, *et al.*, "A Systematic Review of Health Economic Models of Opioid Agonist Therapies in Maintenance Treatment of Non-Prescription Opioid Dependence," *Addiction Science & Clinical Practice*, 12(6), 2017; H. Cranmer, *et al.*, "Health-Related Quality of Life in Opioid Use Disorder Measured by Utilities: A Systematic Literature Review," *Value in Health*, 19(7), 2016 A387; J. De Maeyer, ,

similar numbers does not materially change the value of the ratio. There is also considerable variation in the estimates for each condition reducing the reliability of any weighting.

85. Furthermore, analgesics could not be expected to fully restore quality of life for affected patients – in part because the analgesics are unlikely to fully eliminate pain,[117] in part due to side effects (such as constipation) from opioid treatment,[118] and in part because these patients are affected by other symptoms aside from pain – so the actual QALY benefits from treatment would be lower than studies of the utility loss from pain would suggest.

86. In sum, I take a similar approach to the quality-of-life impact of opioids as I did with productivity effects. As in the case of assessing productivity effects, the purpose of my analysis is to determine whether overall costs from shipments exceed ostensible benefits. I can again simplify the analysis by making conservative assumptions. In terms of quality-of-life impacts, I am of the opinion that any quality of life gains from pain relief are more than offset by increased disease burden association with OUD In the face of ratios of costs to benefits of 4.5 to 1 or 7 to 1, to be conservative, when it comes to tallying the economic impact of opioid shipments on quality of life, I will assume the ratio is just one-to-one leading the costs to just

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W. Vanderplasschen and E. Broekaert, "Quality of Life Among Opiate-Dependent Individuals: A Review of the Literature," *International Journal of Drug Policy*, 21(5), 2010, pp. 364-380; and J. P. Feelemyer, *et al.*, "Changes in Quality of Life (WHOQOL-BREF) and Addiction Severity Index (ASI) Among Participants in Opioid Substitution Treatment (OST) in *Low and Middle Income Countries: An International Systematic Review," Drug and Alcohol Dependence*, 134, 2014, pp. 251-258.

[117] A study by Dillie *et al.* (2008) finds very low health-related quality of life of chronic pain patients who are treated with opioids relative to US population norms; see K.S. Dillie *et al*., "Quality of Life Associated with Daily Opioid Therapy in a Primary Care Chronic Pain Sample," *J Am Board Fam Med*, 21(2), 2008, pp. 108-117. See also M.R. Kosinski, *et al.*, "An observational study of health-related quality of life and pain outcomes in chronic low back pain patients treated with fentanyl transdermal system," *Current Medical Research and Opinion*, 21(6), 2005, pp. 849-862.

[118] F. Hjalte, *et al*., "Treatment of Severe Pain and Opioid-induced Constipation: An Observational Study of Quality of Life, Resource Use, and Costs in Sweden," *Pain Ther*, 5, 2016, pp. 227-236.

balance out the benefits. This is conservative because the evidence implies that the costs more than outweigh the benefits.

87. I implement this conservative assumption in my valuing of the net costs of opioid shipments in Section IV by not counting cost associated with quality-of-life reductions due to OUD and its *sequelae*. Not counting this cost certainly offsets any benefits of opioid shipments on pain relief and quality of life.

88. Summary of reasonableness/unreasonableness of shipments. From two perspectives, shipments of prescription opioids are unreasonable. First, nationally, less than 10% of shipments over the period 2006-2016 could have been devoted to clinically appropriate use.

89. Second, from the economic standpoint of costs and benefits, shipments were also unreasonable. Positive productivity and quality-of-life effects of scientifically acceptable pain treatment are vastly outweighed by the negative effects on productivity and quality of life. The net social contribution of shipments of prescription opioids is negative and large.

D. Defendants Were or Should Have Been Aware of the Interference

90. As explained in the expert reports of Dr. Perri referenced above, as well as the expert reports of Dr. David Kessler and Dr. David Egilman, the Manufacturing Defendants knew or should have known that they were making misleading statements about the safety and efficacy of the prescription opioids they manufactured. For instance, marketing by the Defendants was consistent in conveying the message that the risk of addiction in patients taking opioids for pain was minimal; that tolerance, dependence, and addiction were not serious concerns; and that opioids were the safest and most effective treatment for chronic/long-term pain. These reports

further establish that there was no basis, however, for Defendants to make these misleading statements.

91. In addition, based on my own examination of publicly available documents and discovery produced in this litigation, Defendants had clear knowledge that the shipments had negative impacts on the public health and safety of communities across the nation, including in the Bellwether communities.

92. For example, in connection with Purdue's 2007 settlement with the United States Government mentioned above, Purdue entered into an "Agreed Statement of Facts" in which Purdue admitted that from December 12, 1995 to June 30, 2001, "certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications …"[119] Furthermore, Purdue acknowledged that it "manufactured, marketed, and sold quantities of OxyContin in interstate commerce from various locations …"[120]

93. Additionally, in connection with Mallinckrodt's 2017 settlement with the Department of Justice mentioned above, Mallinckrodt entered into an "Administrative Memorandum of Agreement" which indicates that "[f]rom January 1, 2008, through September 30, 2011, there was an epidemic increase in diversion of the controlled substance oxycodone" and that "[t]he

[119] Agreed Statement of Facts, United States of America v. The Purdue Frederick Company, Inc., United States District Court for the Western District of Virginia, Arlington Division, (available at http://i.bnet.com/blogs/purdue-agreed-facts.pdf), ¶ 20.

[120] *Ibid.,* ¶ 44.

United States alleges that Mallinckrodt, a manufacturer and distributor of oxycodone, knew about the diversion and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion."[121] Furthermore, the "Acceptance of Responsibility" section of the agreement indicates that "Mallinckrodt agrees that at certain times during the Covered Time Period prior to January 1, 2012, certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA …"[122]

94. As set forth above, both Cardinal and McKesson also entered into settlement agreements with the Department of Justice arising out of their failures to adhere to DEA regulations regarding the effective control over the controlled substances they distributed.[123] In particular, I understand both of these settlements were reached after the government alleged that these distributors' conduct allowed the diversion of millions of prescription opioids from legitimate to non-legitimate channels, thereby placing these entities on notice that they knew or should have known their conduct was causing a substantial interference to the public health and safety of the Bellwether communities.

95. I understand from counsel that the distributors' knowledge about the diversion, abuse, and misuse potential of the prescription opioids they distributed across the country, including

[121] Administrative Memorandum of Agreement between the United States Department of Justice, Drug Enforcement Administration and Mallinckrodt, plc, p. 1, available at https://www.justice.gov/usao-edmi/press-release/file/986026/download.

[122] *Ibid.*, pp. 3-4.

[123] https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html; https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html

in Ohio and in the Bellwether communities will be further spelled out in other evidence and expert testimony.

E. Conclusion

96. Section III establishes that first, shipments of prescription opioids significantly interfered with the public health, safety and peace in the Bellwether communities. Second, shipments were unreasonable from the standpoint of being primarily directed to use without clinical justification and from the standpoint of the costs vastly outweighing the benefits. By my calculations, explained in detail in Section IV, the net economic cost of prescription opioid shipments to the two Bellwether counties over the 11-year period 2006-2016 approximately $20 billion. Third, Defendants were aware of the addictive and other harmful effects of prescription opioids.

97. Defendants' shipments of prescription opioids meet the criteria for a public nuisance contained in ¶¶ 7-8 above. I conclude that Defendants' shipment and distribution of prescription opioids constituted a public nuisance.

IV. Quantification of the Magnitude of the Economic Costs Imposed on Bellwether Communities by Prescription Opioid Shipments

98. In this section, I address the third part of my assignment, quantifying, in dollar terms, the net economic costs imposed on the Bellwether communities by shipments of prescription opioids. To put my analysis in context, I begin with a review of some published studies quantifying some elements of the economic burden of opioids. Then, after discussion of the general economic framework for assessing the harms in dollar terms, I conduct a series of

analyses to quantify the net economic harm in the Bellwether communities. Throughout this Section, valued harms are *due to Defendants' shipments of prescription opioids,* as described in Section III.B.

A. Review of Some Earlier Studies of Economic Burden of the Opioid Crisis

99. A variety of published studies estimate the cost of the opioid crisis in the United States. These studies review the economic cost of the opioid epidemic in terms of health care costs, criminal justice costs, lost productivity, and the cost of premature death.

100. In 2016, Curtis S. Florence and colleagues from the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC) set out "[t]o estimate the economic burden of prescription opioid overdose, abuse, and dependence from a societal perspective" across the United States for the year 2013.[124] To that end, Florence *et al.* (2016) analyzed three areas of impact: 1) health care costs, 2) criminal justice costs, and 3) lost productivity costs. For health care costs, the authors utilized de-identified medical claims data from Truven Health MarketScan® for commercial, Medicaid and Medicare health plan enrollees, while also accounting for SUD treatment costs not paid by health insurance (and therefore not in the MarketScan data), such as public programs like SAMHSA grants and private funding. Criminal justice costs included police protection, legal and adjudication, correctional facilities, and property loss due to crime. Lost productivity costs included costs from premature death due to opioid abuse, reduced productive hours due to abuse/dependence, and incarceration.

[124] Florence *et al.*, op. cit.

101. This analysis resulted in an estimated total economic burden of prescription opioid abuse, dependence, and overdose of $78.5 billion nationwide in 2013. More than one third of that estimated $78.5 billion, the authors concluded, was "due to increased health care and substance abuse treatment costs," with one quarter of the overall nationwide cost borne by public sector health care, substance abuse treatment, and criminal justice costs.[125]

102. In November 2017, as a part of the Trump Administration's investigation into the impact of the opioid crisis, the Council of Economic Advisers ("CEA") issued a report entitled "The Underestimated Cost of the Opioid Crisis."[126] The CEA study focused not just on prescription opioid abuse, dependence, and overdose, as previous studies – including the CDC's – had, but also on illicit opioid abuse, including heroin. However, the study noted that of individuals presenting with an OUD in 2015, just 14% presented with heroin use disorder with no prescription opioid involvement.[127] The study also quantified "the costs of opioid-related overdose deaths based on economic valuations of fatality risk reduction," known as "value of statistical life" (in line with what I do here and discussed in more below), which is commonly used to measure fatality risk-reduction benefits used by federal agencies.[128]

103. Taking into account the 33,091 opioid-related deaths, as well as the reported 2.4 million individuals suffering with OUD in 2015, the CEA estimated economic costs of $431.7 billion

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[125] Florence, *et al.*, *op. cit.*

[126] The Council of Economic Advisers (CEA), Executive Office of the President of the United States, "The Underestimated Cost of the Opioid Crisis," November 2017, available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf.

[127] *Ibid.*, p. 7.

[128] *Ibid.*, p. 3.

resulting from fatalities (more than 85% of total costs), and $72.3 billion for non-fatal disease. In total, the CEA estimated the cost of the opioid crisis at more than half a trillion dollars ($504 billion) for 2015 – more than six times greater than that estimated by Florence *et al.* (2016) for 2013 – signaling the quantitative importance of valuing a death in assessing the cost of opioids.

104. Results from the Florence *et al.* (2016) and CEA studies are listed in Table 3, along with a summary of other national studies.

Table 3
Summary of National Studies of the Societal Costs Attributable to Opioids

Study	Year[7]	Opioids[8]	Cost Categories Included	Total Cost (billions)
Birnbaum et al. (2006) [1]	2001	Prescription	Healthcare (treatment, excess medical costs), Workplace Costs (premature death, reduced wages/employment, incarceration), Criminal Justice (police, legal, corrections)	$8.6
Hansen et al. (2011)[2]	2006	Prescription	Healthcare (treatment, medical complications), Productivity Loss (premature death, unemployment/ subemployment, incarceration), Criminal Justice (police, legal, incarceration, costs to crime victims)	$53.4
Birnbaum et al. (2011)[3]	2009	Prescription	Healthcare (treatment, excess medical costs, prevention, research), Workplace Costs (premature death, lost wages/employment, incarceration, excess absenteeism, excess disability, presenteeism), Criminal Justice (police, legal, corrections, lost property)	$55.7
Florence et al. (2016)[4]	2013	Prescription	Healthcare (treatment, excess medical costs), Lost Productivity (reduced productive time/increased disability, incarceration), Criminal Justice (police, legal, corrections, lost property), Fatal costs (lost productivity, healthcare)	$78.5
The Council of Economic Advisors (2017)[5]	2015	Prescription, Illicit	Healthcare (treatment, excess medical costs), Lost Productivity (reduced productive time/increased disability, incarceration), Criminal Justice (police, legal, corrections, lost property), Fatality costs	$504.0
Rhyan (2017)[6]	2016	Prescripton, Illicit	Healthcare (overdoses, indirect), Productivity (fatal, nonfatal), Criminal Justice, Child and Family Assistance, Education	$95.3

Sources:

[1] Birnbaum, Howard G., et al., "Estimated Costs of Prescription Opioid Analgesic Abuse in the United States in 2001," *Clin J Pain* , Volume 22, Number 8, October 2006.

[2] Hansen, Ryan N, et al., "Economic Costs of Nonmedical Use of Prescription Opioids," Clin J Pain, Volume 27, Number 3, March/April 2011.

[3] Birnbaum, Howard G., et al., "Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States," Pain Medicine, 2011, 12:657-667.

[4] Florence, Curtis S., et al., "The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependance in the United States, 2013," Medical Care, Volume 54, Number 10, October 2016.

[5] The Council of Economic Advisers, "The Underestimated Cost of the Opioid Crisis," November 2017.

[6] Rhyan, Corwin N., "The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, and Substance Use Disorders Exceeds $95 Billion Per Year," Altarum, November 16, 2017.

[7] The year listed reflects the year in which dollar cost estimates are measured, not necessarily the year from which the data originate.

[8] The Birnbaum et al., (2006), Birnbaum et al., (2011) and Florence et al. (2016) articles estimate costs for prescription opioids, however, their estimates of excess healthcare costs cannot distinguish between individuals who abuse prescription and illicit opioids.

105. Studies of costs of the opioid crisis have been conducted at the state and local level within Ohio. In October 2017, the Ohio-based C. William Swank Program in Rural-Urban Policy

published "Taking Measure of Ohio's Opioid Crisis."[129] The Swank Report studied costs in four categories: (1) health care and treatment costs, (2) criminal justice costs, (3) lost productivity among current users, and (4) lost productivity of overdose deaths. Depending on the assumptions made about the rate of non-fatal opioid addiction and abuse, the authors estimated the costs to Ohio in 2015 to range from $6.6 to $8.8 billion.[130]

106. A community assessment of the impact of the opioid crisis undertaken in Lorain County, just to the west of Cuyahoga County, concluded that "annual economic burden of the opioid crisis in Lorain County reached nearly $200 million in 2016."[131] Categories of economic burden studied include lost earnings and productivity and increased costs for health care, criminal justice, children and family services, treatment and prevention.[132]

B. Economic Framework for Valuing Harms in Dollar Terms

107. In Section III, I report some of the harms due to shipments of prescription opioids in "natural units" – *i.e.*, number of deaths, cases of disease, babies born with NAS, number of

[129] Swank Program in Rural-Urban Policy, "Taking Measure of Ohio's Opioid Crisis," October 2017, available at https://cpb-us-w2.wpmucdn.com/u.osu.edu/dist/2/14548/files/2017/10/SWANK-Taking-Measure-of-Ohios-Opioid-Crisis-1vtx548.pdf.

[130] The lower-bound estimate is derived from the survey response data from the NSDUH, which, as noted earlier, likely underestimates the true rates of disease in Ohio. The Report factors up the Ohio rate to reflect this likely undercount to get the upper-bound estimate. See Swank Report, page 1.

[131] "Community Assessment of the Opioid Crisis in Lorain County, Ohio: Executive Summary," Prepared for The Nord Family Foundation, December 20, 2017, available at https://altarum.org/sites/default/files/uploaded-publication-files/Lorain-County-Community-Assessment_Executive-Summary.pdf.

[132] Brill and Ganz estimated state and county level per-capita costs of the opioid crisis by allocating CEA's national estimates to states and counties using variations local costs, such as wages and health care as well as local variations in opioid-related factors such as mortality and morbidity. They estimated the total cost per-capita for Ohio to be $3,385, which ranks fourth in the United States. A. Brill and S.Ganz, "The Geographic Variation in the Cost of the Opioid Crisis," American Enterprise Institute, AEI Economics Working Paper 2018-03, March 2018.

crimes, and a count of children needing foster care placement. Economic analysis often, however, requires a summing of effects in common units, and economists use dollars to do so.

108. Valuing effects or inputs in dollar terms is sometimes straightforward. For example, labor and other inputs are used to prevent crime. To find the total cost of such activities to prevent crime, one could add the public sector spending (*e.g.*, some community policing costs, some public education costs) to what individuals and groups buy privately (*e.g.*, guards, equipment). In an application of the economist's concept of "opportunity costs," these labor and other inputs are traded on markets, and market prices are available to measure the value of inputs in dollar terms.[133]

109. In other circumstances, market prices are not available to value inputs or effects in dollars. No market price directly values death, crime victimization, suffering with illness, or the cost of a maltreated child. In these circumstances, economists have developed methods to substitute for market prices. For example, economists use tradeoffs workers make of wages for risk of death to infer the value they put on risk of death.[134] Economists use jury awards for pain and suffering to put a dollar value on the subjective cost of crime to a victim.[135]

110. As needed in this section, when markets are absent, I will describe and employ conventional economic methods to value effects in dollars. The overarching goal is to "add up"

[133] Opportunity cost refers to value in the best alternative use. Prices set on competitive markets equal opportunity cost.

[134] See, for example, U.S. Department of Health and Human Services. 2016. "Guidelines for Regulatory Impact Analysis," available at https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

[135] T.R. Miller, M.A. Cohen and S.B. Rossman. "Victim costs of violent crime and resulting injuries," *Health Affairs*, 1993,12(4), pp. 186-197. M.A. Cohen, "Pain, Suffering, and Jury Awards: A Study of the Cost of Crime to Victims," *Law & Society Review*, 1988, 22(3), pp. 537-556.

in dollar terms the economic cost of the many forms of harmful effects due to by shipments of prescription opioids into the Bellwether communities.

C. Overview of Categories of Harms and Methods of Valuation

111. Table 4 summarizes the categories of harms valued in this section. I put dollar values on the deaths, cases of OUD, babies born with NAS, crimes,[136] and child maltreatment attributable to shipments. Bellwether government costs, the final category in the table and a form of harm measured in dollars, were discussed and estimated in my Damages Report.[137]

112. OUD creates harms in multiple ways, including reducing productivity and reducing quality of life, as well as increasing health care costs. As explained above, I do not count productivity losses from OUD in Table 4 because I use these costs to more than offset any productivity gains associated with opioid treatment. I also do not count any quality-of-life losses associated with OUD because I use these costs to more than offset any quality of life gains from pain reduction. Table 4 is thus a net and conservative accounting of the economic cost of the harms caused by shipments of prescription opioids.

[136] Criminal justice and police costs are accounted for in the analysis of Bellwether government costs. The source of these is the damages analyses above.

[137] See McGuire Damages Report, Section V.

Table 4
Categories of Harms Due to Shipments and Method of Valuation

Form of Harm	Method Used for Valuation	Primary Sources for Valuation
Mortality: Deaths	Value of statistical life (VSL)	U.S. Health and Human Services guidance
Morbidity: OUD Cases	Elevated health care costs	Review of relevant literature
Babies with NAS	Elevated health care costs	Review of relevant literature
Crimes	Valuation	Review of relevant literature
Child Maltreatment	Elevated costs	Review of relevant literature
Bellwether Government Costs	Elevated costs	McGuire Report on Damages

D. Valuation in Dollar Terms: Mortality

113. An accounting of the economic cost of a death can be made with the economic concept of the value of a "statistical life," used by researchers and government agencies to assign a dollar value to the economic cost of a death.[138] I rely on guidance from the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS) and choose $9.3 million as the national value of a statistical life (VSL) in 2014. Appendix C explains some of the methodology and sources behind this estimate.[139]

[138] The Value of a Statistical Life (VSL) is figured as the ratio of the maximum willingness to pay for a given reduction in the probability risk of death within a specified time period. This yields a monetary amount per statistical life saved. For example, if I were willing to pay $10,000 to avoid a 1/100 risk of death, the VSL would be measured as $10,000*100 = $10m. See L. Robinson and J. Hammitt "Valuing Reductions in Fatal Illness Risks: Implications of Recent Research," *Health Economics*, 2016, 25, pp 1039-1052. The methodology for measuring the VSL is discussed in more detail in Appendix C.

[139] The VSL incorporates lost productivity from death so no separate accounting of lost productivity is necessary when VSL is applied to value the costs of mortality. "VSL is expected to be larger than expected productivity loss, because it includes the utility gains from living in addition to productivity and market consumption." Robinson and Hammitt, *op. cit.*, p. 1041.

114. The national value of $9.3 million in 2014 can be adjusted to different years and different geographic areas. Since the VSL derives from consumer preferences, factors affecting willingness to pay affect the estimate of the VSL for particular local areas in particular years. Appendix C explains how differences in income and price levels are used to estimate VSL for different years for Cuyahoga and Summit counties.

115. The first rows of Tables 5a and 5b show for each county the number of deaths due to shipments in each year for each county applying the results from Professor Cutler's analysis explained above. The last two rows of the tables show, for each year and Bellwether, the VSL and the product of the VSL and the number of deaths due to shipments. This product is the economic harm from deaths. Over this 11-year time period, this measure of the economic value of lost lives is $16.7 billion for the two counties. As in the CEA Report discussed above,[140] the value of lives lost comprises the largest component of the economic harm from opioid shipments.

Table 5a
Mortality and Valuation of Mortality Due to Opioid Shipments
Cuyahoga County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Opioid Overdose Deaths	104	87	111	92	138	185	191	223	234	245	504	2,114
Share of Harm Due to Shipments	49.2%	50.4%	51.1%	52.4%	54.6%	57.6%	66.5%	74.3%	80.9%	87.3%	90.7%	
Opioid Deaths Due to Shipments	51	44	57	48	75	107	127	166	189	214	457	1,535
VSL ($mil)	$5.9	$6.6	$6.8	$6.0	$6.3	$6.6	$6.8	$7.2	$7.5	$7.7	$8.1	
Valuation ($mil)	$302	$289	$387	$289	$478	$702	$864	$1,199	$1,413	$1,655	$3,702	$11,279

See Appendix C for sources and calculation notes.

[140] CEA, op. cit.

Table 5b
Mortality and Valuation of Mortality Due to Opioid Shipments
Summit County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Opioid Overdose Deaths	25	31	21	23	45	34	60	56	105	135	269	804
Share of Harm Due to Shipments	49.2%	50.4%	51.1%	52.4%	54.6%	57.6%	66.5%	74.3%	80.9%	87.3%	90.7%	
Opioid Deaths Due to Shipments	12	16	11	12	25	20	40	42	85	118	244	623
VSL ($mil)	$6.5	$7.1	$7.8	$7.3	$7.2	$7.6	$8.2	$8.4	$8.7	$8.9	$9.1	
Valuation ($mil)	$80	$111	$83	$88	$176	$148	$326	$348	$740	$1,048	$2,229	$5,377

See Appendix C for sources and calculation notes.

E. Valuation in Dollar Terms: Morbidity

116. I conservatively value the net economic effects of shipment-caused morbidity in terms of higher health care costs only. The opioid epidemic has increased health care utilization. Individuals with OUD consume more health care both to treat their OUD (*e.g.*, addiction services, MAT, etc.) and to treat comorbidities, such as hepatitis C and HIV, which occur in greater frequencies among patients with OUD.[141] In this section, I estimate the additional health care costs attributable to opioid shipments.

117. Researchers examining the additional health care costs resulting from OUD have measured the magnitude of excess health care costs due to OUD using a "cost-of-illness" methodology. The basic approach is to compare the health care costs of individuals with OUD to a comparison group of individuals with similar insurance, sociodemographic and other characteristics. The goal of the comparison is to estimate the costs for all health care, not just

[141] J. S. Morrison and L. Dattilo, "America's Dangerous Syndemic: Opioid Addiction, HIV, and Hepatitis C," *Center for Strategic & International Studies*, December 2017; P.J. Peters, *et al.*, "HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014-2015," *The New England Journal of Medicine*, July 21, 2016, pp. 229-239; Nilsen, E., "America's opioid crisis has become and 'epidemic of epidemics,'" *Vox*, March 6, 2018, available at https://www.vox.com/2018/3/6/16453530america-opioid-crisis-epidemic-bacterial-endocarditis-hepatitis-c.

OUD treatment, resulting from OUD after controlling for other health factors. So, for example, suppose there are two 40-year-old men with private insurance. One man suffers from OUD and the second man does not. These analyses compare the health care spending over 12 months for these two men, starting at the time of the first OUD diagnosis for the individual with OUD. The difference in their health care spending is the excess health care cost attributable to OUD.

Table 6
Literature Documenting the Elevated Health Care Costs of OUD

Study	Year[7]	Patient Population Studied	Additional Annual Cost for OUD Individuals
Birnbaum et al., (2006)[1]	2001	Commercial	$9,449
		Publicly Insured	$12,394
		Uninsured	$4,566
McAdam-Marx et al., (2010)[2]	2002-2003	Medicaid	$5,874
White et al., (2005)[3]	2003	Commerical	$14,054
Rice et al., (2014)[4]	2012	Commercial	$11,376
Florence et al., (2016)[5]	2013	Commerical	$15,500
		Medicare	$17,052
		Medicaid	$13,743
Kirson et al., (2017)[6]	2015	Commercial	$14,810

[1] Birnbuam, Howard G., Alan G. White, Jennifer L. Reynolds, Paul E. Greenberg, Mingliang Zhang, Sue Vallow, Jeff R. Schein, Nathanial P. Katz, "Estimated Costs of Prescription Opioid Analgesic Abuse in the United States in 2001," *Clin J Pain* , Volume 22, Number 8, October 2006.

[2] McAdam-Marx, Carrie, Carl L. Roland, Jody Cleveland, Gary M. Oderda, "Costs of Opioid Abuse and Misuse Determined From a Medicaid Database," *Journal of Pain & Palliative Care Pharmacotherapy* , 24:1, 5-18.

[3] White, Alan G., Howard G. Birnbaum, Milena N. Mareva, Maham Daher, Susan Vallow, Jeff Schein, Nathaniel Katz, "Direct Costs of Opioid Abuse in an Insured Population in the United States," *J Manag Care Pharm* , 2005:11(6):469-79.

[4] Rice, J. Bradford, Noam Y. Kirson, Amie Shei, Caroline J. Enloe, Alice Kate G. Cummings, Howard G. Birnbaum, Pamela Holly, and Rami Ben-Joseph. "The Economic Burden of Diagnosed Opioid Abuse Among Commercially Insured Individuals, *Postgraduate Medicine* , Volume 126, Issue 4, July/August 2014.

[5] Florence, Curtis S., Chao Zhou, Feijun Luo, and Likang Xu, "The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013." *Medical Care* , Vol 54, No. 10, 2016.

[6]Kirson, Noam Y., Lauren M. Scarpati, Caroline J. Enloe, Aliya P. Dincer, Howard G. Birnbaum, and Tracy J. Mayne. "The Economic Burden of Opioid Abuse: Updated Findings." *J Manag Care Spec Pharm* . 2017;23(4):427-45.

[7] The year listed reflects the year in which dollar cost estimates are measured, not necessarily the year from which the data originate.

118. Despite some differences in population covered, form of health insurance, definition of OUD, and the chosen comparison group, there is a rough consensus from the research literature that the additional health care costs for an individual with OUD in the 2006 through

2016 period range from approximately $11,000 to $17,000 per patient per year.[142] (See Table 6). Florence *et al.* (2016) use the same "cost of illness" methodology to estimate the excess health care costs attributable to OUD for patients with Medicare, Medicaid and private insurance in 2013.[143] They find that health care costs were $15,500 higher for commercially insured patients, $17,052 higher for Medicare patients, and $13,743 higher for Medicaid patients.

119. I use the Florence *et al.* (2016) findings, along with the number of person-years with OUD estimated in Tables 7a and 7b to estimate excess health care costs attributable to OUD in the Bellwether counties. As explained in detail in Appendix H, I estimate the number of OUD individuals covered by Medicare, Medicaid and private insurance plans from national surveys. I multiply the number of OUD person-years in each insurance category by the excess health care costs attributable to OUD in each year, adjusted for health care inflation. Excess health care costs were $1.4 billion for individuals with OUD in Cuyahoga County and $587 million for individuals with OUD in Summit County. See Tables 7a and 7b.

[142] Conceptually, these studies all use this matching methodology to compare health care costs, however, there are small differences between the studies. For example, studies may use different slightly different measurement periods or may use different numbers of control patients.

[143] Florence *et al.* (2016) use Truven Health MarketScan Research Databases for commercial, Medicaid and Medicare enrollees. They identify OUD individuals using ICD-9-CM codes for opioid abuse, dependence or overdose, which include costs due to prescription opioid or heroin dependence. All individuals included in the study had 18 months of continuous insurance coverage in the data. The first six months of data were used for matching OUD to non-OUD individuals and the final 12 months were used for cost comparison. Florence *et al.* (2016), p. 902.

Table 7a
Morbidity and Valuation of Morbidity Due to Shipments
Cuyahoga County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Prevalence of OUD	1.18%	1.15%	1.19%	1.36%	1.38%	1.42%	1.55%	1.48%	1.53%	1.44%	1.40%	
County Population 12 + (000s)	1,117.2	1,109.9	1,103.5	1,099.4	1,094.7	1,089.4	1,087.5	1,087.9	1,086.8	1,083.7	1,080.9	12,040.8
Persons with OUD (000s)	13.2	12.7	13.2	14.9	15.1	15.4	16.8	16.1	16.6	15.6	15.1	164.8
Share of Harm Due to Shipments	49.2%	50.4%	51.1%	52.4%	54.6%	57.6%	66.5%	74.3%	80.9%	87.3%	90.7%	
Persons with OUD Due to Opioid Shipments (000s)	6.5	6.4	6.7	7.8	8.2	8.9	11.2	12.0	13.4	13.6	13.7	108.5
Elevated Health Costs ($mil)	$65	$67	$72	$87	$95	$107	$142	$158	$185	$194	$205	$1,376

See Appendix D for sources and calculation notes.

Table 7b
Morbidity and Valuation of Morbidity Due to Shipments
Summit County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Prevalence of OUD	1.18%	1.15%	1.19%	1.36%	1.38%	1.42%	1.55%	1.48%	1.53%	1.44%	1.40%	
County Population 12 + (000s)	461.9	462.5	462.6	462.5	463.0	463.8	464.4	465.7	466.5	466.4	466.1	5,105.5
Persons with OUD (000s)	5.5	5.3	5.5	6.3	6.4	6.6	7.2	6.9	7.1	6.7	6.5	70.0
Share of Harm Due to Shipments	49.2%	50.4%	51.1%	52.4%	54.6%	57.6%	66.5%	74.3%	80.9%	87.3%	90.7%	
Persons with OUD Due to Opioid Shipments (000s)	2.7	2.7	2.8	3.3	3.5	3.8	4.8	5.1	5.8	5.9	5.9	46.2
Elevated Health Costs ($mil)	$27	$28	$30	$37	$40	$46	$60	$68	$79	$84	$88	$587

See Appendix D for sources and calculation notes.

F. Valuation in Dollar Terms: Children Born with NAS

120. Due to data limitations, valuing the harms due to NAS in this section is confined to excess hospital costs associated with birth. While the dollar amount of harms due to neonatal abstinence syndrome described in this Report is small relative to other costs attributable to opioid shipments, these adverse effects are likely to be vastly underestimated relative to the full costs over the course of a child's lifetime. Firstly, in addition to health care costs, cases of NAS may also require monitoring and follow-up by child welfare services, which results in

increased labor costs.[144] Additionally, there may be longer-term adverse outcomes associated with NAS. While the effects of NAS on long-term outcomes are more difficult to study due to confounding factors associated with opioid use and abuse, there is compelling evidence that NAS is associated with several adverse outcomes in infancy and childhood, including neurodevelopmental and neurobehavioral impairment,[145] maltreatment,[146] mental and behavioral disorders,[147] and visual impairment.[148] Children with NAS have also been found to have impaired school performance,[149] and to be at increased risk for educational disability and needing special education services,[150] relative to comparison children. All of these harms

[144] U.L. França, S. Mustafa and M.L. McManus, "The Growing Burden of Neonatal Opiate Exposure on Children and Family Services in Massachusetts," *Child Maltreatment*, 2011 21(1), pp. 80-84.

[145] R.W. Hunt, *et al.*, "Adverse neurodevelopmental outcome of infants exposed to opiate in-utero," *Early Human Development*, 2008, 84(1), pp. 29-35; L. McGlone and H. Mactier, "Infants of opioid-dependent mothers: neurodevelopment at six months," *Early Human Development*, 2015, 91(1), pp. 19-21; E. Nygaard, *et al.*, "Longitudinal cognitive development of children born to mothers with opioid and polysubstance use," *Pediatric Research*, 2015, 78(3), pp. 330-335; A. Baldacchino *et al.*, "Erratum: neurobehavioral consequences of chronic intrauterine opioid exposure in infants and preschool children: a systematic review and meta-analysis," *BMC Psychiatry*, 2015, 15(1), p. 134; T.S. Rosen and H.L. Johnson, "Children of methadone-maintained mothers: follow-up to 18 months of age," *The Journal of Pediatrics*, 101(2), 1982, pp. 192-196; R. Bunikowski, *et al.,* "Neurodevelopmental outcome after prenatal exposure to opiates," *European Journal of Pediatrics*, 1998, 157(9), pp. 724-730.

[146] Uebel et al., op. cit.

[147] Uebel et al., op. cit.

[148] L. McGlone *et al.*, "Visual outcome in infants born to drug-misusing mothers prescribed methadone in pregnancy," *British Journal of Ophthalmology*, 2014, 98(2), pp. 238-245; R. Hamilton, *et al.*, "Ophthalmic, clinical and visual electrophysiological findings in children born to mothers prescribed substitute methadone in pregnancy," *British Journal of Ophthalmology*, 2010, 94(6), pp. 696-700; K.S. Cornish, *et al.*, "The short-and long-term effects on the visual system of children following exposure to maternal substance misuse in pregnancy," *American Journal of Ophthalmology*, 2013, 156(1), pp. 190-194; Uebel *et al.*, *op. cit*.

[149] J.L. Oei, *et al.*, "Neonatal abstinence syndrome and high school performance," *Pediatrics*, 2017, 139(2), e20162651, pp. 1-10.

[150] M.A. Fill, *et al.*, "Educational disabilities among children born with neonatal abstinence syndrome," *Pediatrics*, 2018, 142(3), e20180562.

represent additional social costs of opioid use that have not, due to data limitations, been quantified in this Report.

121. A NAS birth is associated with more intensive hospital utilization than other births, including, for example, increased length of stay and increased risk of admission to the neonatal intensive care unit, resulting in excess costs.[151]

122. To quantify the excess hospital charges due to NAS, I use the difference between the average hospital charge for an NAS case in Ohio and the average hospital charge for all births in Ohio in each year, as reported in Ohio Department of Health statewide data.[152] These excess hospital charges are reported in Tables 8a and 8b below. I then use these excess hospital charges to estimate excess hospital costs by multiplying charges by net revenue-to-charge ratios from the American Hospital Association. Tables 8a and 8b report the total estimated hospital costs of NAS attributable to opioid shipments; these costs were $9.4 million in Cuyahoga County and $6.7 million in Summit county between 2006-2016.

Table 8a
Neonatal Abstinence Syndrome (NAS) and Valuation
Cuyahoga County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Opioid-Related NAS Cases	19	23	30	45	60	74	94	117	117	117	141	837
Share of Harm Due to Shipments	49.2%	50.4%	51.1%	52.4%	54.6%	57.6%	66.5%	74.3%	80.9%	87.3%	90.7%	
NAS Cases Due to Shipments	9	12	15	24	33	43	62	87	95	102	128	609
Excess Hospital Costs Due to NAS	$12,885	$19,525	$18,795	$22,276	$18,587	$15,731	$14,671	$15,153	$16,823	$14,011	$13,397	
Valuation of NAS Health Costs Due to Shipments ($ mil)	$0.12	$0.23	$0.29	$0.53	$0.61	$0.67	$0.91	$1.32	$1.59	$1.43	$1.71	$9.41

See Appendix E for sources and calculation notes.

[151] Wong *et al.*, *op. cit.* See also: T.E. Corr and C.S. Hollenbeak, "The Economic Burden of Neonatal Abstinence Syndrome in the United States," *Addiction*, 2017, 112, pp. 1590-1599.

[152] See Appendix E.

Table 8b
Neonatal Abstinence Syndrome (NAS) and Valuation
Summit County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Opioid-Related NAS Cases	13	16	20	31	41	50	63	89	89	89	89	589
Share of Harm Due to Shipments	49.2%	50.4%	51.1%	52.4%	54.6%	57.6%	66.5%	74.3%	80.9%	87.3%	90.7%	
NAS Cases Due to Shipments	6	8	10	16	22	29	42	66	72	77	81	430
Excess Hospital Costs Due to NAS	$12,885	$19,525	$18,795	$22,276	$18,587	$15,731	$14,671	$15,153	$16,823	$14,011	$13,397	
Valuation of NAS Health Costs Due to Shipments ($ mil)	$0.08	$0.16	$0.20	$0.36	$0.41	$0.45	$0.62	$1.00	$1.21	$1.08	$1.08	$6.65

See Appendix E for sources and calculation notes.

G. Valuation in Dollar Terms: Crime

123. Appendix F describes the methods I use for counting the number of crimes in the Bellwether communities due to shipments of prescription opioids, and for valuing the cost of crimes in dollars. In terms of counting crimes, I begin with a standard database reporting number of crimes by category of crime; specifically, I calculate the total criminal activity reported for all reporting Law Enforcement Agencies in the National Incident-Based Reporting System (NIBRS) data in which the 'primary county' listed is Cuyahoga/Summit. I then apply methods from Professor Cutler's report to attribute a share of those crimes to shipments of opioids.

124. A useful framework used in the economic literature on crime classifies costs into direct, indirect, and intangible costs.[153] Direct costs include the costs of private crime deterrents (alarms, security), public expenditures on police, and the value of property lost due to criminal activity. Indirect costs of crime include the productivity loss for victims of violent crime and the

[153] Two literature reviews are N. Wickramasekera, *et al.*, "Cost of crime: A systematic review," *Journal of Criminal Justice*, 2015, 43(3), pp. 218-228 and K.E. McCollister, M.T. French and H. Fang, "The cost of crime to society: New crime-specific estimates for policy and program evaluation," 2010, 108(1-2), pp. 98-109.

loss in productivity due to addiction and incarceration for the perpetrator. Finally, intangible costs consist of pain, suffering, and psychological consequences borne by crime victims and the public. Details on the dollar valuation are also contained in Appendix F.

125. Direct costs of crime, such as property loss, medical care expenses, and public or private expenditures on crime deterrents, are often estimated by combining several sources of data, including government data on criminal justice system costs, surveys on medical expenses, and property loss associated with crime.[154] The main component of the indirect costs of crime is productivity loss of both the victims and the perpetrators. Crimes that result in injury or hospitalization lead to a reduction in victim productivity. The opportunity cost to criminals of engaging in productive activities by criminals is also included in the indirect cost of crime.[155] Finally, intangible costs include the pain, emotional and psychological consequences of criminal activity imposed on victims and the public. The "jury-compensation approach" uses monetary amounts awarded by juries in injury cases, net of medical costs and lost wages, to estimate intangible costs to victims.[156] A second method for estimating intangible costs, the contingent valuation approach, uses surveys to estimate respondents' willingness-to-pay for reductions in hypothetical risk of pain, suffering or various types of crimes.

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[154] See D.A. Anderson, "The cost of crime," Foundations and Trends® in Microeconomics 7.3 (2012): 209-265, chapter 4, for a discussion and a representative example of the data-aggregation methods used in crime costing studies.

[155] These costs are often calculated by multiplying the minimum wage or other unskilled labor wage by the amount of time spent by criminals in incarceration. Note this assumes incarcerated individuals would work full time if not incarcerated. While this is a crude measure, is its likely an underestimation of this form of crime cost, because there it does not include the opportunity cost of crime that does not result in incarceration. See S. Aos, *et al.* "The Comparative Costs and Benefits of Programs to Reduce Crime. Version 4.0," (2001) for a discussion of this point.

[156] This methodology was developed in M.A. Cohen(1988), *op cit.*

126. To avoid any double counting of costs of crime already accounted for in the budget impacts on the Bellwether governments, I deduct from costs the direct costs to the criminal justice system. This is conservative because crime in a county imposes direct costs not just on the county government but also on other governments with criminal jurisdiction within the county, such as, in this case, the city governments of Akron and Cleveland. Criminal justice costs of crime for the Bellwether county governments are included in the costs reported in Table 11 below.

127. Tables 9a and 9b present dollar estimates of the costs of crime, across all types of offenses, per Bellwether county and year due to shipments. These figures include direct, indirect and intangible costs as described above. In total, I estimate that shipments from 2006-2016 led to $327 million in Cuyahoga county, and $126 million in Summit county.

Table 9a
Crime and Valuation of Crime Due to Shipments
Cuyahoga County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Crimes	2,636	2,531	3,082	3,155	3,498	3,728	4,648	4,641	4,932	5,441	5,665	43,957
Valuation of Crimes ($mil)	$19	$19	$22	$23	$25	$25	$32	$33	$35	$43	$50	$327

See Appendix F for sources and calculation notes.

Table 9b
Crime and Valuation of Crime Due to Shipments
Summit County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Crimes	934	903	1,275	1,350	1,556	1,616	1,918	2,324	2,600	3,021	3,281	20,779
Valuation of Crimes ($mil)	$6	$6	$8	$8	$9	$10	$12	$13	$16	$18	$20	$126

See Appendix F for sources and calculation notes.

H. Valuation in Dollar Terms: Child Maltreatment

128. Appendix G describes the methods I use for counting the number of victims of child maltreatment in the Bellwether communities due to shipments of prescription opioids, and for valuing the excess costs incurred. In terms of counting victims, I rely on Dr. Young's reporting of the number of victims of substantiated maltreatment in the two counties. I then apply methods from Professor Cutler's report to attribute a share of these victims to shipments of opioids.

129. The research literature establishes that child maltreatment (abuse or neglect) devastates a child, lowering educational attainment;[157] reducing cognitive development;[158] increasing the need for special education services;[159] lowering employment and earnings;[160]

[157] R. Gilbert, *et al*, "Burden and consequences of child maltreatment in high-income countries," *The Lancet,* 373, 2009, 68-81; J. Currie and C.S. Widom, "Long-term consequences of child abuse and neglect on adult economic well-being," *Child Maltreatment*, 15(2), 2010, pp. 111-120; J.P. Mersky and J. Topitzes, "Comparing early adult outcomes of maltreated and non-maltreated children: A prospective longitudinal investigation," *Children and Youth Services Review*, 32(8), 2010, pp. 1086-1096; Doyle & Aizer, 2018, *op. cit.;* A. Bald, E. Chyn, J.S. Hastings, and M. Machelett, "The Causal Impact of Removing Children from Abusive and Neglectful Homes," NBER Working Paper 25419, January 2019.

[158] K.L. Hildyard and D.A. Wolfe, "Child neglect: developmental issues and outcomes," *Child Abuse & Neglect,* 26, 2002, pp. 679-695; C.M. Perez and C.S. Widom, "Childhood victimization and long-term intellectual and academic outcomes," *Child Abuse & Neglect,* 18(8), 1994, pp. 617-633; J. Currie & C.S. Widom, 2010, *op. cit.*

[159] M. Jonson-Reid, *et al.*, "A prospective analysis of the relationship between reported child maltreatment and special education eligibility among poor children," *Child Maltreatment,* 9(4), 2004, pp. 382-394; R.J. Gelles and S. Perlman, "Estimated Annual Cost of Child Abuse and Neglect," Prevent Child Abuse America; April 2012, available at https://preventchildabuse.org/wp-content/uploads/2016/02/PCA_COM2012-1.pdf; R. Gilbert *et al.,* 2009, *op. cit.*

[160] R.J. Gelles & S. Perlman, 2012, *op. cit.;* R. Gilbert *et al.,* 2009, *op. cit.;* J. Currie & C.S. Widom, 2010, *op. cit.;* J.P. Mersky and J. Topitzes, 2010, *op. cit.*

and causing higher rates of preventable deaths,[161] obesity,[162] depression,[163] substance abuse,[164] and PTSD.[165] Furthermore maltreatment elevates rates of juvenile delinquency[166] and crime.[167] These negative effects of maltreatment are costly.

130. I focus on the research studies of lost earnings and special education costs, as these are the outcomes for which there is strong evidence of adverse effects due to childhood maltreatment. Again, to avoid double counting with the costs reported in Table 11 below, I do not include excess crime-related costs for the victims of maltreatment.

131. For each outcome of interest, I first determine the estimated incremental effect of maltreatment on the outcome. For example, maltreated children are 8.6 percentage points

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[161] A. Hjern, B. Vinnerljung, and F. Lindblad, "Avoidable mortality among child welfare recipients and intercountry adoptees: a national cohort study," *Journal of Epidemiology & Community Health,* 58(5), 2004, pp. 412-417; Doyle & Aizer, 2018, *op. cit.*

[162] L.M. Berger and J. Waldfogel, "Economic Determinants and Consequences of Child Maltreatment," OECD Social, Employment and Migration Working Paper No. 111, April 2011, OECD Publishing, Paris, available at http://dx.doi.org/10.1787/5kgf09zj7h9t-en; R. Gilbert *et al.,* 2009, *op. cit.*

[163] L.M. Berger and J. Waldfogel, 2011, *op. cit.;* R. Gilbert *et al.,* 2009, *op. cit.;* A. Bald, E. Chyn, J.S. Hastings, and M. Machelett, 2019, *op. cit.;* F. Wulczyn, 2009, *op. cit.;* J.P. Mersky and J. Topitzes, 2010, *op. cit.*; C.S. Widom, K. DuMont, and S.J. Czaja, "A prospective investigation of major depressive disorder and comorbidity in abused and neglected children grown up," *Archives of General Psychiatry*, 64(1), 2007, pp. 49-56.

[164] L.M. Berger and J. Waldfogel, 2011, *op. cit.*; R. Gilbert *et al.,* 2009, *op. cit.*; F. Wulczyn, 2009, *op. cit.*; J.P. Mersky and J. Topitzes, 2010, *op. cit.*; C.S. Widom, K. DuMont, and S.J. Czaja, 2007, *op. cit.*

[165] L.M. Berger and J. Waldfogel, 2011, *op. cit.*; R. Gilbert *et al.,* 2009, *op. cit.*; C.S. Widom, K. DuMont, and S.J. Czaja, 2007, *op. cit.*; C.S. Widom, "Posttraumatic stress disorder in abused and neglected children grown up," *American Journal of Psychiatry,* 156(8), 1999, pp. 1223-1229.

[166] C.S. Widom, "The Cycle of Violence," *Science*, 244(4901), 1989, pp. 160-166; R.J. Gelles & S. Perlman, 2012, *op. cit.*; R. Gilbert *et al.,* 2009, *op. cit.*; M.G. Maxfield and C.S. Widom, "The cycle of violence: Revisited 6 years later," *Archives of Pediatrics & Adolescent Medicine*, 150(4), 1996, pp. 390-395; C.S. Widom and M.G. Maxfield, "An Update on the 'Cycle of Violence.' Research in Brief," Department of Justice, Washington, DC, National Institute of Justice; February 2001, available at https://files.eric.ed.gov/fulltext/ED451313.pdf.

[167] J. Currie and E. Tekin, "Does child abuse cause crime?" NBER Working Paper 12171, April 2006; Doyle & Aizer, 2018, *op. cit.*; R.J. Gelles & S. Perlman, 2012, *op. cit.*; R. Gilbert *et al.,* 2009, *op. cit.*; Widom, 1989, *op. cit.*; J. Currie and E. Tekin, "Understanding the cycle childhood maltreatment and future crime," *Journal of Human Resources,* 47(2), 2012, pp. 509-549; J.P. Mersky and J. Topitzes, 2010, *op. cit.*; M.G. Maxfield and C.S. Widom, 1996, *op. cit*; C.S. Widom and M.G. Maxfield, 2001, *op. cit.*

more likely to need special education services compared with control children (22.3% vs. 13.7%).[168] Following methodology by Fang *et al.* (2012),[169] I multiply the total estimated cost of special education services by 0.086 to arrive at an estimate of the excess special education costs for each case of childhood maltreatment. See Appendix G for additional details on these and other components of the estimates and the literature on the social costs of childhood maltreatment.

132. Tables 10a and 10b report the dollar estimates of the cost of child maltreatment for the two Bellwether communities, using the counts of maltreatment from Section III. I estimate that the social costs of cases of maltreatment attributable to opioid shipments between 2006-2016 is $401 million for Cuyahoga and $297 million for Summit counties.[170] Lost earnings (*i.e.*, productivity losses) are the largest component of costs.

Table 10a
Child Maltreatment Cases and Valuation Due to Shipments
Cuyahoga County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Number of Cases of Maltreatment	2,043	1,924	2,073	1,452	1,738	2,092	2,156	2,502	2,281	2,316	2,513	23,090
Share Harms Due to Opioid Shipments	2.2%	2.7%	3.2%	3.7%	4.0%	4.2%	4.8%	6.6%	8.2%	9.6%	13.5%	
Maltreatment Cases Due to Opioid Shipments	45	52	65	53	70	88	104	164	186	222	340	1,391
Social Cost of Maltreatment by Category												
Productivity Losses ($000s)	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	
Special Education Costs ($000s)	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	
Total Social Costs ($000s)	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	
Valuation of Child Maltreatment ($mil)	$13.1	$14.9	$18.9	$15.4	$20.1	$25.4	$29.9	$47.3	$53.7	$64.0	$97.9	$400.6

See Appendix G for sources and calculation notes.

[168] M. Jonson-Reid, *et al.*, 2004, *op. cit.*

[169] X. Fang, *et al.*, "The economic burden of child maltreatment in the United States and implications for prevention," *Child Abuse & Neglect*, 2012, 36, pp. 156-165.

[170] See Appendix G for further details on these calculations.

Table 10b
Child Maltreatment and Valuation Due to Shipments
Summit County, 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Number of Cases of Maltreatment	1,319	1,117	901	944	715	643	674	601	579	757	886	9,136
Share Harms Due to Opioid Shipments	2.1%	2.6%	3.3%	4.6%	12.0%	12.2%	15.5%	18.3%	19.5%	21.8%	27.5%	
Maltreatment Cases Due to Opioid Shipments	28	29	30	44	86	79	105	110	113	165	244	1,031
Social Cost of Maltreatment by Category												
Productivity Losses ($000s)	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	$286.0	
Special Education Costs ($000s)	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	$1.95	
Total Social Costs ($000s)	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	$288.0	
Valuation of Child Maltreatment ($mil)	$8.1	$8.2	$8.6	$12.6	$24.7	$22.6	$30.1	$31.7	$32.5	$47.6	$70.1	$296.9

See Appendix G for sources and calculation notes.

I. Bellwether Government Costs Due to Shipments

133. My Damages Report estimates the costs incurred by the Bellwether governments as a result of opioid shipments due to misconduct. As detailed in that report, I identified government divisions impacted by the opioid crisis and the costs within those divisions that were potentially affected by the opioid crisis.[171] To those estimates of potentially affected costs, I applied shares of harm due to Defendants' misconduct estimated by Professor Cutler and report my estimates of costs incurred by the Bellwether governments as a result of Defendants' misconduct.[172]

134. As discussed above, in this Report, I focus on all opioid shipments when assessing costs (not just the share of shipments Professor Rosenthal attributed to misconduct). Appendix E to my Damages Report included these estimates,[173] and they are reproduced here as Table 11.

[171] See, McGuire Damages Report, Sections III and IV.

[172] See McGuire Damages Report, Section V.

[173] See McGuire Damages Report, Appendix IV.E. Tables E.3 and E4.

Bellwether county costs attributable to shipments totaled $172.4 million for Cuyahoga and $98.7 million for Summit over the period 2006-2016.

Table 11
Government Costs Attributable to Opioid Shipments
2006-2016 (millions)

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total
Cuyahoga County ($mil)	$6.4	$7.4	$9.5	$10.4	$11.7	$12.7	$14.7	$18.9	$22.1	$25.7	$32.9	$172.4
Summit County ($mil)	$2.0	$2.2	$2.9	$4.1	$8.0	$7.9	$9.5	$12.4	$14.0	$15.9	$19.8	$98.7
Total ($mil)	$8.4	$9.6	$12.4	$14.5	$19.8	$20.5	$24.3	$31.3	$36.1	$41.6	$52.7	$271.1

Sources: McGuire Cost Report, Tables E.3 and E.4.

J. Sum of Economic Costs Imposed on Bellwether Communities Due to Shipments

135. Table 12 summarizes the costs to the Bellwether communities from the five categories of harm assess here, excess mortality, morbidity, babies born with NAS, crime, and cases of child maltreatment. In addition, Table 12 includes the costs to the county governments in Cuyahoga and Summit tallied in my Damages Report. In total, over the 11-year period, shipments of prescription opioids imposed net economic costs on the Bellwether communities of approximately $13.6 billion in Cuyahoga and approximately $6.5 billion for Summit. Harms include those associated with heroin, fentanyl and other drugs to the degree that harms from these drugs can be attributed to shipments of prescription opioids.

136. These results are conservative for two reasons (in addition to the reasons discussed above that apply to component estimates.) First, the accounting stops in 2016 because of data limitations. Some categories of costs could be estimated for later years, but to keep the results consistent across cost categories, I only included costs through 2016 in the tables. The harms due to opioid shipments are ongoing and are much higher in the later years, after the crisis

accelerated, compared to the earlier years. Costs to Cuyahoga in 2016 alone were almost $4.1 billion and to Summit were approximately $2.4 billion. Costs for 2016 represent reasonable estimates of costs for 2017 and 2018 and could be added to the total if required.

137. The second reason is that not all categories of costs are included in the five categories assessed here. Costs not counted here include costs to other governments in the counties, such as the City of Cleveland, the City of Akron, school districts and other public agencies. Also not counted, among other categories, are losses in property values and property taxes due to opioid-related crime, and losses in sales taxes.

Table 12
Summary of Harms Due to Shipments Valued in Dollars, 2006-2016
(millions)

Form of Harm	Method of Valuation	Cuyahoga	Summit	Total
Mortality: Deaths	Value of statistical life (VSL)	$11,279	$5,377	$16,656
Morbidity: OUD Cases	Elevated health care costs	$1,376	$587	$1,963
Babies with NAS	Elevated health care costs	$9	$7	$16
Crimes	Valuation	$327	$126	$453
Child Maltreatment	Elevated costs	$401	$297	$698
Bellwether Government Costs	Elevated costs	$172	$99	$271
Totals		***$13,564***	***$6,492***	***$20,056***

Sources: Tables 5a, 5b, 7a, 7b, 8a, 8b, 9a, 9b, 10a, 10b and 11 of this Report.

138. As noted above in ¶ 45, I only report results using Dr. Cutler's Approach 1 in this Report. Appendix I includes all the tables resulting from my analysis using Dr. Cutler's Approach 2. Table 13 below summarizes the results from reliance on Approach 2.

Table 13
Summary of Monetary Value of Harms Due to Prescription Opioid Shipments
Based on Dr. Cutler's Approach 2
2006-2016 (millions)

Form of Harm	Method of Valuation	Cuyahoga	Summit	Total
Mortality: Deaths	Value of statistical life (VSL)	$13,306	$6,059	$19,366
Morbidity: OUD Cases	Elevated health care costs	$1,738	$739	$2,477
Babies with NAS	Elevated health care costs	$11	$8	$19
Crimes	Valuation	$420	$159	$579
Child Maltreatment	Elevated costs	$485	$360	$845
Bellwether Government Costs	Elevated costs	$215	$119	$334
Totals		***$16,176***	***$7,445***	***$23,621***

Sources: Tables I.5a, I.5b, I.7a, I.7b, I.8a, I.8b, I.9a, I.9b, I.10a, I.10b and I.11 of Appendix I.

March 25, 2019

Prof. Thomas McGuire